



COMPILATION OF SELECTED ACTS WITHIN
THE JURISDICTION OF THE COMMITTEE
ON COMMERCE

HEALTH LAW

As Amended Through June 30, 1995

INCLUDING

PUBLIC HEALTH SERVICE ACT
DEVELOPMENTAL DISABILITIES ASSISTANCE AND BILL OF
RIGHTS ACT
MENTAL HEALTH SYSTEMS ACT
CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT
OF 1981
DRUG ABUSE PREVENTION, TREATMENT, AND REHABILITA-
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ALZHEIMER'S DISEASE AND RELATED DEMENTIAS
RESEARCH ACT OF 1992
ABANDONED INFANTS ASSISTANCE ACT OF 1988
MISCELLANEOUS PROVISIONS

PREPARED FOR THE USE OF THE

COMMITTEE ON COMMERCE
U.S. HOUSE OF REPRESENTATIVES



JULY 1995

U.S. DEPT. OF HEALTH & HUMAN SERVICES
Office Of The General Counsel
Health Care Financing Division

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JULY 1995

U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON : 1995

90-940

For sale by the U.S. Government Printing Office
Superintendent of Documents, Mail Stop: SSOP, Washington, DC 20402-9328
ISBN 0-16-047403-5

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PUBLIC HEALTH SERVICE ACT

NOTE.—Reorganization Plan No. 3 of 1966 transferred all statutory powers and functions of the Surgeon General and other officers of the Public Health Service and of all agencies of or in the Service to the Secretary of Health, Education, and Welfare. The Department of Education Organization Act designated the Secretary of Health, Education, and Welfare as the Secretary of Health and Human Services. References in the Act to the Surgeon General, other officers of the Service, the Secretary of Health, Education, and Welfare, and the Department of Health, Education, and Welfare, should be read in the light of the transfer of statutory functions and the redesignation.



PUBLIC HEALTH SERVICE ACT

(As Amended Through June 30, 1995)

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PUBLIC HEALTH SERVICE ACT

(References in brackets [] are to title 42, United States Code)

TITLE I—SHORT TITLE AND DEFINITIONS

SHORT TITLE

SECTION 1. [201 note] This Act may be cited as the “Public Health Service Act”.

DEFINITIONS

SEC. 2. [201] When used in this Act—

(a) The term “Service” means the Public Health Service;

(b) The term “Surgeon General” means the Surgeon General of the Public Health Service;

(c) Unless the context otherwise requires, the term “Secretary” means the Secretary of Health and Human Services;

(d) The term “regulations”, except when otherwise specified, means rules and regulations made by the Surgeon General with the approval of the Secretary;

(e) The term “executive department” means any executive department, agency, or independent establishment of the United States or any corporation wholly owned by the United States;

(f) Except as provided in sections 314(g)(4)(B), 318(c)(1), 331(h)(3), 335(5), 361(d), 701(9), 1002(c), 1401(13), 1531(1), and 1633(1), the term “State” includes, in addition to the several States, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

(g) The term “possession” includes, among other possessions, Puerto Rico and the Virgin Islands;

(h) [Repealed.]

(i) The term “vessel” includes every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on water, exclusive of aircraft and amphibious contrivances;

(j) The term “habit-forming narcotic drug” or “narcotic” means opium and coca leaves and the several alkaloids derived therefrom, the best known of these alkaloids being morphia, heroin, and cocaine, obtained from opium, and cocaine derived from the coca plant; all compounds, salts, preparations, or other derivatives obtained either from the raw material or from the various alkaloids; Indian hemp and its various derivatives, compounds, and preparations, and peyote in its various forms; isonipecaine and its derivatives, compounds, salts and preparations; opiates (as defined in section 3228(f) of the Internal Revenue Code);

(k) The term "addict" means any person who habitually uses any habit-forming narcotic drugs so as to endanger the public morals, health, safety, or welfare, or who is or has been so far addicted to the use of such habit-forming narcotic drugs as to have lost the power of self-control with reference to his addiction;

(l) The term "psychiatric disorders" includes diseases of the nervous system which affect mental health;

(m) The term "State mental health authority" means the State health authority, except that, in the case of any State in which there is a single State agency, other than the State health authority, charged with responsibility for administering the mental health program of the State, it means such other State agency;

(n) The term "heart diseases" means diseases of the heart and circulation;

(o) The term "dental diseases and conditions" means diseases and conditions affecting teeth and their supporting structures, and other related diseases of the mouth;

(p) The term "uniformed service" means the Army, Navy, Air Force, Marine Corps, Coast Guard, Public Health Service, or Coast and Geodetic Survey; and

(q) The term "drug dependent person" means a person who is using a controlled substance (as defined in section 102 of the Controlled Substances Act) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

TITLE II—ADMINISTRATION AND MISCELLANEOUS PROVISIONS

PART A—ADMINISTRATION

PUBLIC HEALTH SERVICE

SEC. 201. [202] The Public Health Service in the Department of Health and Human Services shall be administered by the Assistant Secretary for Health under the supervision and direction of the Secretary.

ORGANIZATION

SEC. 202.¹ [203] The Service shall consist of (1) the Office of the Surgeon General, (2) the National Institutes of Health, (3) the Bureau of Medical Services, and (4) the Bureau of State Services, and² the Agency for Health Care Policy and Research.³ The Secretary is authorized and directed to assign to the Office of the Secretary, to the National Institutes of Health, to the Bureau of Medical Services, and to the Bureau of State Services, respectively, the several functions of the Service, and to establish within them such divisions, sections and other units as he may find necessary; and from time to time, abolish, transfer, and consolidate divisions, sections, and other units and assign their functions and personnel in such manner as he may find necessary for efficient operation of the Service. No division shall be established, abolished, or transferred, and no divisions shall be consolidated, except with the approval of the Secretary. The National Institutes of Health shall be administered as a part of the field service. The Secretary may delegate to any officer or employee of the Service such of his powers and duties under this Act, except the making of regulations, as he may deem necessary or expedient.

COMMISSIONED CORPS

SEC. 203. [204] There shall be in the Service a commissioned Regular Corps and, for the purpose of securing a reserve for duty in the Service in time of national emergency, a Reserve Corps. All

¹The organizational units specified in this section (other than the Agency for Health Care Policy and Research) were all abolished as *statutory* entities by Reorganization Plan No. 3 of 1966. *But see* title IV of this Act (added by section 2 of Public Law 99-158), which provides in section 401(a) that the National Institutes of Health is an agency of the Public Health Service and which further provides in section 402(a) that the President shall appoint the Director of the National Institutes of Health. Although the Reorganization Plan abolished the National Institutes of Health as an agency, it did not abolish the individual research institutes.

²So in law. See section 2008(g)(2) of Public Law 103-43 (107 Stat. 212). The term "the Agency" probably should be preceded by "(5)", and the "and" before "(4)" probably should be struck.

³Section 501(a) provides that the Substance Abuse and Mental Health Services Administration "is an agency of the Service". Although not established in this Act, the Centers for Disease Control and Prevention is an agency of the Service, as is the Health Resources and Services Administration.

commissioned officers shall be citizens and shall be appointed without regard to the civil-service laws and compensated without regard to the Classification Act of 1923,¹ as amended. Commissioned officers of the Reserve Corps shall be appointed by the President and commissioned officers of the Regular Corps shall be appointed by him by and with the advice and consent of the Senate. Commissioned officers of the Reserve Corps shall at all times be subject to call to active duty by the Surgeon General, including active duty for the purpose of training and active duty for the purpose of determining their fitness for appointment in the Regular Corps. Warrant officers may be appointed to the Service for the purpose of providing support to the health and delivery systems maintained by the Service and any warrant officer appointed to the Service shall be considered for purposes of this Act and title 37, United States Code, to be a commissioned officer within the commissioned corps of the Service.

SURGEON GENERAL

SEC. 204.² [205] The Surgeon General shall be appointed from the Regular Corps for a four-year term by the President by and with the advice and consent of the Senate. The Surgeon General shall be appointed from individuals who (1) are members of the Regular Corps, and (2) have specialized training or significant experience in public health programs. Upon the expiration of such term, the Surgeon General, unless reappointed, shall revert to the grade and number in the Regular or Reserve Corps that he would have occupied had he not served as Surgeon General.

DEPUTY SURGEON GENERAL AND ASSISTANT SURGEONS GENERAL

SEC. 205.² [206] (a) The Surgeon General shall assign one commissioned officer from the Regular Corps to administer the Office of the Surgeon General, to act as Surgeon General during the absence or disability of the Surgeon General or in the event of a vacancy in that office, and to perform such other duties as the Surgeon General may prescribe, and while so assigned he shall have the title of Deputy Surgeon General.

(b) The Surgeon General shall assign eight commissioned officers from the Regular Corps to be, respectively, the Director of the National Institutes of Health, the Chief of the Bureau of State Services, the Chief of the Bureau of Medical Services, the Chief Medical Officer of the United States Coast Guard, the Chief Dental Officer of the Service, the Chief Nurse Officer of the Service, the Chief Pharmacist Officer of the Service, and the Chief Sanitary Engineering Officer of the Service, and while so serving they shall each have the title of Assistant Surgeon General.

(c)(1) The Surgeon General, with the approval of the Secretary, is authorized to create special temporary positions in the grade of Assistant Surgeons General when necessary for the proper staffing of the Service. The Surgeon General may assign officers of either the Regular Corps or the Reserve Corps to any such temporary po-

¹ Civil service and classification laws are now codified to title 5, United States Code.

² See footnote 1 on page 9.

sition, and while so serving they shall each have the title of Assistant Surgeon General.

(2) Except as provided in this paragraph, the number of special temporary positions created by the Surgeon General under paragraph (1) shall not on any day exceed 1 per centum of the highest number, during the ninety days preceding such day, of officers of the Regular Corps on active duty and officers of the Reserve Corps on active duty for more than thirty days. If on any day the number of such special temporary positions exceeds such 1 per centum limitations, for a period of not more than one year after such day, the number of such special temporary positions shall be reduced for purposes of complying with such 1 per centum limitation only by the resignation, retirement, death, or transfer to a position of a lower grade, of any officer holding any such temporary position.

(d) The Surgeon General shall designate the Assistant Surgeon General who shall serve as Surgeon General in case of absence or disability, or vacancy in the offices, of both the Surgeon General and the Deputy Surgeon General.

GRADES, RANKS, AND TITLES OF THE COMMISSIONED CORPS

SEC. 206. [207] (a) The Surgeon General during the period of his appointment as such, shall be of the same grade as the Surgeon General of the army; the Deputy Surgeon General and the Chief Medical Officer of the United States Coast Guard, while assigned as such, shall have the grade corresponding with the grade of major general; and the Chief Dental Officer, while assigned as such, shall have the grade as is prescribed by law for the officer of the Dental Corps selected and appointed as Assistant Surgeon General of the Army. During the period of appointment to the position of Assistant Secretary for Health, a commissioned officer of the Public Health Service shall have the grade corresponding to the grade of General of the Army. Assistant Surgeons General, while assigned as such, shall have the grade corresponding with either the grade of brigadier general or the grade of major general, as may be determined by the Secretary after considering the importance of the duties to be performed: *Provided*, That the number of Assistant Surgeons General having a grade higher than that corresponding to the grade of brigadier general shall at no time exceed one-half of the number of positions created by subsection (b) of section 205 or pursuant to subsection (c) of such section. The grades of commissioned officers of the Service shall correspond with grades of officers of the Army as follows:

- (1) Officers of the director grade—colonel;
- (2) Officers of the senior grade—lieutenant colonel;
- (3) Officers of the full grade—major;
- (4) Officers of the senior assistant grade—captain;
- (5) Officers of the assistant grade—first lieutenant;
- (6) Officers of the junior assistant grade—second lieutenant;
- (7) Chief warrant officers of (W-4) grade—chief warrant officer (W-4);
- (8) Chief warrant officers of (W-3) grade—chief warrant officer (W-3);

(9) Chief warrant officers of (W-2) grade—chief warrant officer (W-2); and

(10) Warrant officers of (W-1) grade—warrant officer (W-1).

(b) The titles of medical officers of the foregoing grades shall be respectively (1) medical director, (2) senior surgeon, (3) surgeon, (4) senior assistant surgeon, (5) assistant surgeon and (6) junior assistant surgeon.

(c) The President is authorized to prescribe titles, appropriate to the several grades, for commissioned officers of the Service other than medical officers. All titles of the officers of the Reserve Corps shall have the suffix "Reserve".

(d) Within the total number of officers of the Regular Corps authorized by the appropriation Act or Acts for each fiscal year to be on active duty, the Secretary shall by regulation prescribe the maximum number of officers authorized to be in each of the grades from the warrant officer (W-1) grade to the director grade, inclusive. Such numbers shall be determined after considering the anticipated needs of the Service during the fiscal year, the funds available, the number of officers in each grade at the beginning of the fiscal year, and the anticipated appointments, the anticipated promotions based on years of service, and the anticipated retirements during the fiscal year. The number so determined for any grade for a fiscal year may not exceed the number limitation (if any) contained in the appropriation Act or Acts for such year. Such regulations for each fiscal year shall be prescribed as promptly as possible after the appropriation Act fixing the authorized strength of the corps for that year, and shall be subject to amendment only if such authorized strength or such number limitation is thereafter changed. The maxima established by such regulations shall not require (apart from action pursuant to other provisions of this Act) any officer to be separated from the Service or reduced in grade.

(e) In computing the maximum number of commissioned officers of the Public Health Service authorized by law to hold a grade which corresponds to the grade of brigadier general or major general, there may be excluded from such computation not more than three officers who hold such a grade so long as such officers are assigned to duty and are serving in a policymaking position in the Department of Defense.

APPOINTMENT OF PERSONNEL

SEC. 207. [209] (a)(1) Except as provided in subsections (b) and (e) of this section, original appointments to the Regular Corps may be made only in the warrant officer (W-1), chief warrant officer (W-2), chief warrant officer (W-3), chief warrant officer (W-4), junior assistant, assistant, and senior assistant grades and original appointments to a grade above junior assistant shall be made only after passage of an examination, given in accordance with regulations of the President, in one or more of the several branches of medicine, dentistry, hygiene, sanitary engineering, pharmacy, psychology, nursing, or related scientific specialties in the field of public health.

(2) Original appointments to the Reserve Corps may be made to any grade up to and including the director grade but only after

passage of an examination given in accordance with regulations of the President. Reserve commissions shall be for an indefinite period and may be terminated at any time, as the President may direct.

(3) No individual who has attained the age of forty-four shall be appointed to the Regular Corps, or called to active duty in the Reserve Corps for a period in excess of one year, unless (A) he has had a number of years of active service (as defined in section 211(d)) equal to the number of years by which his age exceeds forty-four, or (B) the Surgeon General determines that he possesses exceptional qualifications, not readily available elsewhere in the Commissioned Corps of the Public Health Service, for the performance of special duties with the Service, or (C) in the case of an officer of the Reserve Corps, the Commissioned Corps of the Service has been declared by the President to be a military service.

(b)(1) Not more than 10 per centum of the original appointments to the Regular Corps authorized to be made during any fiscal year may be made to grades above that of senior assistant, but no such appointment (other than an appointment under section 204) may be made to a grade above that of director. For the purpose of this subsection the number of original appointments authorized to be made during a fiscal year shall be (1) the excess of the number of officers of the Regular Corps authorized by the appropriation Act or Acts for such year over the number of officers on active duty in the Regular Corps on the first day of such year, plus (2) the number of such officers of the Regular Corps who, during such fiscal year, have been or will be retired upon attainment of age sixty-four or have for any other reason ceased to be on active duty. In determining the number of appointments authorized by this subsection an appointment shall be deemed to be made in the fiscal year in which the nomination is transmitted by the President to the Senate.

(2) In addition to the number of original appointments to the Regular Corps authorized by paragraph (1) to be made to grades above that of senior assistant, original appointments authorized to be made to the Regular Corps in any year may be made to grades above that of senior assistant, but not above that of director, in the case of any individual who—

(A)(i) was on active duty in the Regular Corps on July 1, 1960, (ii) was on such active duty continuously for not less than one year immediately prior to such date, and (iii) applies for appointment to the Regular Corps prior to July 1, 1962; or

(B) does not come within clause (A)(i) and (ii) but was on active duty in the Reserve Corps continuously for not less than one year immediately prior to his appointment to the Regular Corps and has not served on active duty continuously for a period, occurring after June 30, 1960, of more than three and one-half years prior to applying for such appointment.

(3) No person shall be appointed pursuant to this subsection unless he meets standards established in accordance with regulations of the President.

(c) Commissions evidencing the appointment by the President of officers of the Regular or Reserve Corps shall be issued by the

Secretary under the seal of the Department of Health, Education, and Welfare.

(d)(1) For purposes of basic pay and for purposes of promotion, any person appointed under subsection (a) to the grade of senior assistant in the Regular Corps and any person appointed under subsection (b), shall, except as provided in paragraphs (2) and (3) of this subsection, be considered as having had on the date of appointment the following length of service: Three years if appointed to the senior assistant grade, ten years if appointed to the full grade, seventeen years if appointed to the senior grade, and eighteen years if appointed to the director grade.

(2) For purposes of basic pay, any person appointed under subsection (a) to the grade of senior assistant in the Regular Corps, and any person appointed under subsection (b), shall, in lieu of the credit provided in paragraph (1), be credited with the service for which he is entitled to credit under any other provision of law if such service exceeds that to which he would be entitled under such paragraph.

(3) For purposes of promotion, any person originally appointed in the Regular Corps to the senior assistant grade or above who has had active service in the Reserve Corps shall be considered as having had on the date of appointment the length of service provided for in paragraph (1), plus whichever of the following is greater: (A) The excess of his total active service in the Reserve Corps (above the grade of junior assistant) over the length of service provided in such paragraph, to the extent that such excess is on account of service in the Reserve Corps in or above the grade to which he is appointed in the Regular Corps or (B) his active service in the same or any higher grade in the Reserve Corps after the first day on which, under regulations in effect on the date of his appointment to the Regular Corps, he would have had the training and experience necessary for such appointment.

(4) For purposes of promotion, any person whose original appointment is to the assistant grade in the Regular Corps shall be considered as having had on the date of appointment service equal to his total active service in the Reserve Corps in and above the assistant grade.

(e)(1) A former officer of the Regular Corps may, if application for appointment is made within two years after the date of the termination of his prior commission in the Regular Corps, be reappointed to the Regular Corps without examination, except as the Surgeon General may otherwise prescribe, and without regard to the numerical limitations of subsection (b).

(2) Reappointments pursuant to this subsection may be made to the permanent grade held by the former officer at the time of the termination of his prior commission, or to the next higher grade if such officer meets the eligibility requirements prescribed by regulation for original appointment to such higher grade. For purposes of pay, promotion, and seniority in grade, such reappointed officer shall receive the credits for service to which he would be entitled if such appointment were an original appointment, but in no event less than the credits he held at the time his prior commission was terminated, except that if such officer is

reappointed to the next higher grade he shall receive no credit for seniority in grade.

(3) No former officer shall be reappointed pursuant to this subsection unless he shall meet such standards as the Secretary may prescribe.

(f) In accordance with regulations, special consultants may be employed to assist and advise in the operations of the Service. Such consultants may be appointed without regard to the civil-service laws and their compensation may be fixed without regard to the Classification Act of 1923, as amended.¹

(g) In accordance with regulations, individual scientists, other than commissioned officers of the Service, may be designated by the Surgeon General to receive fellowships, appointed for duty with the Service without regard to the civil-service laws and compensated without regard to the Classification Act of 1923, as amended,¹ may hold their fellowships under conditions prescribed therein, and may be assigned for studies or investigations either in this country or abroad during the terms of their fellowships.

(h) Persons who are not citizens may be employed as consultants pursuant to subsection (e) and may be appointed to fellowships pursuant to subsection (f). Unless otherwise specifically provided, any prohibition in any other Act against the employment of aliens, or against the payment of compensation to them, shall not be applicable in the case of persons employed or appointed pursuant to such subsections.

(i) The appointment of any officer or employee of the Service made in accordance with the civil-service laws shall be made by the Secretary, and may be made effective as of the date on which such officer or employee enters upon duty.

PAY AND ALLOWANCES

SEC. 208. [210] (a)(1) Commissioned officers of the Regular and Reserve Corps shall be entitled to receive such pay and allowances as are now or may hereafter be authorized by law.

(2)(A) Except as provided in subparagraph (B), commissioned medical and dental officers in the Regular and Reserve Corps shall while on active duty be paid special pay in the same amounts as, and under the same terms and conditions which apply to, the special pay now or hereafter paid to commissioned medical and dental officers of the Armed Forces under chapter 5 of title 37, United States Code.

(B) A commissioned medical officer in the Regular or Reserve Corps (other than an officer serving in the Indian Health Service) may not receive additional special pay under section 302(a)(4) of title 37, United States Code, for any period during which the officer is providing obligated service under (i) section 338B, (ii) section 225(e) (as such section was in effect prior to October 1, 1977), or (iii) section 752 (as such section was in effect between October 1, 1977, and August 13, 1981).

(3) Commissioned nurse officers in the Regular and Reserve Corps shall, while in active duty, be paid incentive special pay in the same amounts as, and under the same terms and conditions

¹See footnote 1 on page 10.

which apply to, the incentive special pay now or hereafter paid to commissioned nurse officers of the Armed Forces under chapter 5 of title 37, United States Code.

(b) Commissioned officers on active duty, and retired officers entitled to retired pay pursuant to section 210(g)(3), section 211 or section 221(a), shall be permitted to purchase supplies from the Army, Navy, Air Force, and Marine Corps at the same price as is charged officers thereof.

(c) Members of the National Advisory Health Council and members of other national advisory or review councils or committees established under this Act, including members of the Technical Electronic Product Radiation Safety Standards Committee and the Board of Regents of the National Library of Medicine, but excluding ex officio members, while attending conferences or meetings of their respective councils or committees or while otherwise serving at the request of the Secretary shall be entitled to receive compensation at rates to be fixed by the Secretary, but at rates not exceeding the daily equivalent of the rate specified at the time of such service for grade GS-18 of the General Schedule, including traveltime; and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently.

(d) Field employees of the Service, except those employed on a per diem or fee basis, who render part-time duty and are also subject to call at any time for services not contemplated in their regular part-time employment, may be paid annual compensation for such part-time duty and, in addition, such fees for such other services as the Surgeon General may determine; but in no case shall the total paid to any such employee for any fiscal year exceed the amount of the minimum annual salary rate of the classification grade of the employee.

(e) Any civilian employee of the Service who is employed at the Gillis W. Long Hansen's Disease Center on the date of the enactment of the Consolidated Omnibus Budget Reconciliation Act of 1985 shall be entitled to receive, in addition to any compensation to which the employee may otherwise be entitled and for so long as the employee remains employed at the Center, an amount equal to one-fourth of such compensation.

(f) Individuals appointed under subsection (g) shall have included in their fellowships such stipends or allowances, including travel and subsistence expenses, as the Surgeon General may deem necessary to procure qualified fellows.

(g) The Secretary is authorized to establish and fix the compensation for, within the Public Health Service, not more than one hundred and seventy-nine positions, of which not less than one hundred and fifteen shall be for the National Institutes of Health, not less than five shall be for the National Institute on Alcohol Abuse and Alcoholism for individuals engaged in research on alcohol and alcoholism, not less than ten shall be for the National Center for Health Services Research, not less than twelve shall be for the National Center for Health Statistics, and not less than seven shall be for the National Center for Health Care Technology, in the

professional, scientific, and executive service, each such position being established to effectuate those research and development activities of the Public Health Service which require the services of specially qualified scientific, professional, and administrative personnel: *Provided*, That the rates of compensation for positions established pursuant to the provisions of this subsection shall not be less than the minimum rate of grade 16 of the General Schedule of the Classification Act of 1949, as amended,¹ nor more than (1) the highest rate of grade 18 of the General Schedule of such Act, or (2) in the case of two such positions, the rate specified, at the time the service in the position is performed, for level II of the Executive Schedule (5 U.S.C. 5313); and such rates of compensation for all positions included in this proviso shall be subject to the approval of the Civil Service Commission. Positions created pursuant to this subsection shall be included in the classified civil service of the United States, but appointments to such positions shall be made without competitive examination upon approval of the proposed appointee's qualifications by the Civil Service Commission or such officers or agents as it may designate for this purpose.

PROFESSIONAL CATEGORIES

SEC. 209. [210b] (a) For the purpose of establishing eligibility of officers of the Regular Corps for promotions, the Surgeon General shall by regulation divide the corps into professional categories. Each category shall, as far as practicable, be based upon one of the subjects of examination set forth in section 207(a)(1) or upon a subdivision of such subject, and the categories shall be designed to group officers by fields of training in such manner that officers in any one grade in any one category will be available for similar duty in the discharge of the several functions of the Service.

(b) Each officer of the Regular Corps on active duty shall, on the basis of his training and experience, be assigned by the Surgeon General to one of the categories established by regulations under subsection (a). Except upon amendment of such regulations, no assignment so made shall be changed unless the Surgeon General finds (1) that the original assignment was erroneous, or (2) that the officer is equally well qualified to serve in another category to which he has requested to be transferred, and that such transfer is in the interests of the Service.

(c) Within the limits fixed by the Secretary in regulations under section 206(d) for any fiscal year, the Surgeon General shall determine for each category in the Regular Corps the maximum number of officers authorized to be in each of the grades from the warrant officer (W-1) grade to the director grade, inclusive.

(d) The excess of the number so fixed for any grade in any category over the number of officers of the Regular Corps on active duty in such grade in such category (including, in the case of the director grade, officers holding such grade in accordance with section 206(c)) shall for the purpose of promotions constitute vacancies in such grade in such category. For purposes of this subsection, an officer who has been temporarily promoted or who is temporarily

¹ See footnote 1 on page 10.

holding the grade of director in accordance with section 206(c) shall be deemed to hold the grade to which so promoted or which he is temporarily holding; but while he holds such promotion or grade, and while any officer is temporarily assigned to a position pursuant to section 205(c), the number fixed under subsection (c) of this section for the grade of his permanent rank shall be reduced by one.

(e) The absence of a vacancy in a grade in a category shall not prevent an appointment to such grade pursuant to section 207, a permanent length of service promotion, or the recall of a retired officer to active duty; but the making of such an appointment, promotion, or recall shall be deemed to fill a vacancy if one exists.

(f) Whenever a vacancy exists in any grade in a category the Surgeon General may increase by one the number fixed by him under subsection (c) for the next lower grade in the same category, without regard to the numbers fixed in regulations under section 206(d); and in that event the vacancy in the higher grade shall not be filled except by a permanent promotion, and upon the making of such promotion the number for the next lower grade shall be reduced by one.

PROMOTIONS AND SEPARATION OF COMMISSIONED OFFICERS IN THE REGULAR CORPS

SEC. 210. [211] (a) Promotions of officers of the Regular Corps to any grade up to and including the director grade shall be either permanent promotions based on length of service, other permanent promotions to fill vacancies, or temporary promotions. Permanent promotions shall be made by the President, by and with the advice and consent of the Senate, and temporary promotions shall be made by the President. Each permanent promotion shall be to the next higher grade, and shall be made only after examination given in accordance with regulations of the President.

(b) The President may by regulation provide that in a specified professional category permanent promotions to the senior grade, or to both the full grade and the senior grade, shall be made only if there are vacancies in such grade. A grade in any category with respect to which such regulations have been issued is referred to in this section as a "restricted grade".

(c) Examinations to determine qualification for permanent promotions may be either noncompetitive or competitive, as the Surgeon General shall in each case determine; except that examinations for promotions to the assistant or senior assistant grade shall in all cases be noncompetitive. The officers to be examined shall be selected by the Surgeon General from the professional category, and in the order of seniority in the grade, from which promotion is to be recommended. In the case of a competitive examination the Surgeon General shall determine in advance of the examination the number (which may be one or more) of officers who, after passing the examination, will be recommended to the President for promotion; but if the examination is one for promotions based on length of service, or is one for promotions to fill vacancies other than vacancies in the director grade or in a restricted grade, such number shall not be less than 80 per centum of the number of officers to be examined.

(d) Officers of the Regular Corps, found pursuant to subsection (c) to be qualified, shall be given permanent promotions based on length of service, as follows:

(1) Officers in the warrant officer (W-1) grade, chief warrant officer (W-2) grade, chief warrant officer (W-3) grade, chief warrant officer (W-4) grade, and junior assistant grade shall be promoted at such times as may be prescribed in regulations of the President.

(2) Officers with permanent rank in the assistant grade, the senior assistant grade, and the full grade shall (except as provided in regulations under subsection (b)) be promoted after completion of three, ten, and seventeen years, respectively, of service in grades above the junior assistant grade; and such promotions, when made, shall be effective, for purposes of pay and seniority in grade, as of the day following the completion of such years of service. An officer with permanent rank in the assistant, senior assistant, or full grade who has not completed such years of service shall be promoted at the same time, and his promotion shall be effective as of the same day, as any officer junior to him in the same grade in the same professional category who is promoted under this paragraph.

(e) Officers in a professional category of the Regular Corps, found pursuant to subsection (c) to be qualified may be given permanent promotions to fill any or all vacancies in such category in the senior assistant grade, the full grade, the senior grade, or the director grade; but no officer who has not had one year of service with permanent or temporary rank in the next lower grade shall be promoted to any restricted grade or to the director grade.

(f) If an officer who has completed the years of service required for promotion to a grade under paragraph (2) of subsection (d) fails to receive such promotion, he shall (unless he has already been twice examined for promotion to such grade) be once reexamined for promotion to such grade. If he is thereupon promoted (otherwise than under subsection (e)), the effective date of such promotion shall be one year later than it would have been but for such failure. Upon the effective date of any permanent promotion of such officer to such grade, he shall be considered as having had only the length of service required for such promotion which he previously failed to receive.

(g) If, for reasons other than physical disability, an officer of the Regular Corps in the warrant officer (W-1) grade or junior assistant grade is found pursuant to subsection (c) not to be qualified for promotion he shall be separated from the Service. If, for reasons other than physical disability, an officer of the Regular Corps in the chief warrant officer (W-2), chief warrant officer (W-3), assistant, senior assistant, or full grade, after having been twice examined for promotion (other than promotion to a restricted grade), fails to be promoted—

(1) if in the chief warrant officer (W-2) or assistant grade he shall be separated from the Service and paid six months' basic pay and allowances;

(2) if in the chief warrant officer (W-3) or senior assistant grade he shall be separated from the Service and paid one year's basic pay and allowances;

(3) if in the full grade he shall be considered as not in line for promotion and shall, at such time thereafter as the Surgeon General may determine, be retired from the Service with retired pay (unless he is entitled to a greater amount by reason of another provision of law)—

(A) in the case of an officer who first became a member of a uniformed service before September 8, 1980, at the rate of $2\frac{1}{2}$ percent of the retired pay base determined under section 1406(h) of title 10, United States Code, for each year, not in excess of 30, of his active commissioned service in the Service; or

(B) in the case of an officer who first became a member of a uniformed service on or after September 8, 1980, at the rate determined by multiplying—

(i) the retired pay base determined under section 1407 of title 10, United States Code; by

(ii) the retired pay multiplier determined under section 1409 of such title for the number of years of his active commissioned service in the Service.

(h) If an officer of the Regular Corps, eligible to take an examination for promotion, refuses to take such examination, he may be separated from the Service in accordance with regulations of the President.

(i) At the end of his first three years of service, the record of each officer of the Regular Corps, originally appointed to the senior assistant grade or above, shall be reviewed in accordance with regulations of the President and, if found not qualified for further service, he shall be separated from the Service and paid six months' pay and allowances.

(j)(1) The order of seniority of officers in a grade in the Regular Corps shall be determined, subject to the provisions of paragraph (2), by the relative length of time spent in active service after the effective date of each such officer's original appointment or permanent promotion in that grade. When permanent promotions of two or more officers to the same grade are effective on the same day, their relative seniority shall be the same as it was in the grade from which promoted. In all other cases of original appointments or permanent promotions (or both) to the same grade effective on the same day, relative seniority shall be determined in accordance with regulations of the President.

(2) In the case of an officer originally appointed in the Regular Corps to the grade of assistant or above, his seniority in the grade to which appointed shall be determined after inclusion, as service in such grade, of any active service in such grade or in any higher grade in the Reserve Corps, but (if the appointment is to the grade of senior assistant or above) only to the extent of whichever of the following is greater: (A) His active service in such grade or any higher grade in the Reserve Corps after the first day on which, under regulations in effect on the date of his appointment to the Regular Corps, he had the training and experience necessary for such appointment, or (B) the excess of his total active service in the Reserve Corps (above the grade of junior assistant) over three years if his appointment in the Regular Corps is to the senior as-

sistant grade, over ten years if the appointment is to the full grade, or over seventeen years if the appointment is to the senior grade.

(k) Any commissioned officer of the Regular Corps in any grade in any professional category may be recommended to the President for temporary promotion to fill a vacancy in any higher grade in such category, up to and including the director grade. In time of war, or of national emergency proclaimed by the President, any commissioned officer of the Regular Corps in any grade in any professional category may be recommended to the President for promotion to any higher grade in such category, up to and including the director grade, whether or not a vacancy exists in such grade. The selection of officers to be recommended for temporary promotions shall be made in accordance with regulations of the President. Promotion of an officer recommended pursuant to this subsection may be made without regard to length of service, without examination, and without vacating his permanent appointment, and shall carry with it the pay and allowances of the grade to which promoted. Such promotions may be terminated at any time, as may be directed by the President.

(l) Whenever the number of officers of the Regular Corps on active duty, plus the number of officers of the Reserve Corps who have been on active duty for thirty days or more, exceeds the authorized strength of the Regular Corps, the Secretary shall determine the requirements of the Service in each grade in each category, based upon the total number of officers so serving on active duty and the tasks being performed by the Service; and the Surgeon General shall thereupon assign each officer of the Reserve Corps on active duty to a professional category. If the Secretary finds that the number of officers fixed under section 209(c) for any grade and category (or the number of officers, including officers of the Reserve Corps, on active duty in such grade in such category, if such number is greater than the number fixed under section 209(c)) is insufficient to meet such requirements of the Service, officers of either the Regular Corps or the Reserve Corps may be recommended for temporary promotion to such grade in such category. Any such promotion may be terminated at any time, as may be directed by the President.

(m) Any officer of the Regular Corps, or any officer of the Reserve Corps on active duty, who is promoted to a higher grade shall, unless he expressly declines such promotion, be deemed for all purposes to have accepted such promotion; and shall not be required to renew his oath of office, or to execute a new affidavit as required by the Act of December 11, 1926, as amended (5 U.S.C. 21a).¹

RETIREMENT OF COMMISSIONED OFFICERS

SEC. 211. [212] (a)(1) A commissioned officer of the Service shall, if he applies for retirement, be retired on or after the first day of the month following the month in which he attains the age of sixty-four years. This paragraph does not permit or require the involuntary retirement of any individual because of the age of the individual.

¹ This Act has been codified to section 3332 of title 5, United States Code.

(2) A commissioned officer of the Service may be retired by the Secretary, and shall be retired if he applies for retirement, on the first day of any month after completion of thirty years of active service.

(3) Any commissioned officer of the Service who has had less than thirty years of active service may be retired by the Secretary, with or without application by the officer, on the first day of any month after completion of twenty or more years of active service of which not less than ten are years of active commissioned service in any of the uniformed services.

(4) Except as provided in paragraph (6), a commissioned officer retired pursuant to paragraph (1), (2), or (3) who was (in the case of an officer in the Reserve Corps) on active duty with the Service on the day preceding such retirement shall be entitled to receive retired pay at the rate of $2\frac{1}{2}$ per centum of the basic pay of the highest grade held by him as such officer and in which, in the case of a temporary promotion to such grade, he has performed active duty for not less than six months, (A) for each year of active service, or (B) if it results in higher retired pay, for each of the following years:

(i) his years of active service (determined without regard to subsection (d)) as a member of a uniformed service; plus

(ii) in the case of a medical or dental officer, four years and, in the case of a medical officer, who has completed one year of medical internship or the equivalent thereof, one additional year, the four years and the one year to be reduced by the period of active service performed during such officer's attendance at medical school or dental school or during his medical internship; plus

(iii) the number of years of service with which he was entitled to be credited for purposes of basic pay on May 31, 1958, or (if higher) on any date prior thereto, reduced by any such year included under clause (i) and further reduced by any such year with which he was entitled to be credited under paragraphs (7) and (8) of section 205(a) of title 37, United States Code, on any date before June 1, 1958;

except that (C) in the case of any officer whose retired pay, so computed, is less than 50 per centum of such basic pay, who retires pursuant to paragraph (1) of this subsection, who has not less than twelve whole years of active service (computed without the application of subsection (e)), and who does not use, for purposes of a retirement annuity under the Civil Service Retirement Act,¹ any service which is also creditable in computing his retired pay from the Service, it shall, instead, be 50 per centum of such pay, and (D) the retired pay of an officer shall in no case be more than 75 per centum of such basic pay.

(5) With the approval of the President, a commissioned officer whose service as Surgeon General, Deputy Surgeon General, or Assistant Surgeon General has totaled four years or more and who has had not less than twenty-five years of active service in the Service may retire voluntarily at any time; and except as provided

¹The Civil Service Retirement Act has been codified to chapter 83 of title 5, United States Code.

in paragraph (6), his retired pay shall be at the rate of 75 per centum of the basic pay of the highest grade held by him as such officer.

(6) The retired pay of a commissioned officer retired under this subsection who first became a member of a uniformed service after September 7, 1980, is determined by multiplying—

(A) the retired pay base determined under section 1407 of title 10, United States Code; by

(B) the retired pay multiplier determined under section 1409 of such title for the number of years of service credited to the officer under paragraph (4).

(7) Retired pay computed under section 210(g)(3) or under paragraph (4) or (5) of this subsection, if not a multiple of \$1, shall be rounded to the next lower multiple of \$1.

(b) For purposes of subsection (a), the basic pay of the highest grade to which a commissioned officer has received a temporary promotion means the basic pay to which he would be entitled if serving on active duty in such grade on the date of his retirement.

(c) A commissioned officer, retired for reasons other than for failure of promotion to the senior grade, may (1) if an officer of the Regular Corps or an officer of the Reserve Corps entitled to retired pay under subsection (a), be involuntarily recalled to active duty during such times as the Commissioned Corps constitutes a branch of the land or naval forces of the United States, and (2) if an officer of either the Regular or Reserve Corps, be recalled to active duty at any time with his consent.

(d) The term "active service", as used in subsection (a), includes:

(1) all active service in any of the uniformed services;

(2) active service with the Public Health Service, other than as a commissioned officer, which the Surgeon General determines is comparable to service performed by commissioned officers of the Service, except that, if there are more than five years of such service only the last five years thereof may be included;

(3) all active service (other than service included under the preceding provisions of this subsection) which is creditable for retirement purposes under laws governing the retirement of members of any of the uniformed services; and

(4) service performed as a member of the Senior Biomedical Research Service established by section 228, except that, if there are more than 5 years of such service, only the last 5 years thereof may be included.

(e) For the purpose of determining the number of years by which a percentage of the basic pay of an officer is to be multiplied in computing the amount of his retired pay pursuant to section 210(g)(3) or paragraph (4) of subsection (a) of this section, each full month of service that is in addition to the number of full years of service credited to an officer is counted as one-twelfth of a year and any remaining fractional part of a month is disregarded.

(f) For purposes of retirement or separation for physical disability under chapter 61 of title 10, United States Code, a commissioned officer of the Service shall be credited, in addition to the service described in section 1208(a)(2) of that title, with active serv-

ice with the Public Health Service, other than as a commissioned officer, which the Surgeon General determines is comparable to service performed by commissioned officers of the Service, except that, if there are more than five years of such service, only the last five years thereof may be so credited. For such purposes, such section 1208(a)(2) shall be applicable to officers of the Regular or Reserve Corps of the Service.

MILITARY BENEFITS

SEC. 212. [213] (a) Except as provided in subsection (b), commissioned officers of the Service and their surviving beneficiaries shall, with respect to active service performed by such officers—

(1) in time of war;

(2) on detail for duty with the Army, Navy, Air Force, Marine Corps, or Coast Guard; or

(3) while the Service is part of the military forces of the United States pursuant to Executive order of the President; be entitled to all rights, privileges, immunities, and benefits now or hereafter provided under any law of the United States in the case of commissioned officers of the Army or their surviving beneficiaries on account of active military service, except retired pay and uniform allowances.

(b) The President may prescribe the conditions under which commissioned officers of the Service may be awarded military ribbons, medals, and decorations.

(c) The authority vested by law in the Department of the Army, the Secretary of the Army, or other officers of the Department of the Army with respect to rights, privileges, immunities, and benefits referred to in subsection (a) shall be exercised, with respect to commissioned officers of the Service, by the Surgeon General.

(d) Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for the purposes of all laws administered by the Secretary of Veterans Affairs (except the Servicemen's Indemnity Act of 1951) and section 217 of the Social Security Act.

(e) Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for the purposes of all rights, privileges, immunities, and benefits now or hereafter provided under the Soldiers' and Sailors' Civil Relief Act of 1940 (50 App. U.S.C. 501 et seq.).

ALLOWANCES FOR UNIFORMS

SEC. 213. [Repealed. ¹]

DETAIL OF PERSONNEL

SEC. 214. [215] (a) The Secretary is authorized, upon the request of the head of an executive department, to detail officers or employees of the Service to such department for duty as agreed upon by the Secretary and the head of such department in order to cooperate in, or conduct work related to, the functions of such

¹ Superseded by section 415(c) of title 37, United States Code.

department or of the Service. When officers or employees are so detailed their salaries and allowances may be paid from working funds established as provided by law or may be paid by the Service from applicable appropriation and reimbursement may be made as agreed upon by the Secretary and the head of the executive department concerned. Officers detailed for duty with the Army, Navy, or Coast Guard shall be subject to the laws for the government of the service to which detailed.

(b) Upon the request of any State health authority or, in the case of work relating to mental health, any State mental health authority, personnel of the Service may be detailed by the Surgeon General for the purpose of assisting such State or political subdivision thereof in work related to the functions of the Service.

(c) The Surgeon General may detail personnel of the Service to any appropriate committee of the Congress or to nonprofit educational research or other institutions engaged in health activities for special studies of scientific problems and for the dissemination of information relating to public health.

(d) Personnel detailed under subsections (b) and (c) shall be paid from applicable appropriations of the Service except that, in accordance with regulations such personnel may be placed on leave without pay and paid by the State, subdivision, or institution to which they are detailed. In the case of detail of personnel under subsections (b) or (c) to be paid from applicable Service appropriations, the Secretary may condition such detail on an agreement by the State, subdivision, or institution concerned that such State, subdivision, or institution concerned shall reimburse the United States for the amount of such payments made by the Service. The services of personnel while detailed pursuant to this section shall be considered as having been performed in the Service for purposes of the computation of basic pay, promotion, retirement, compensation for injury or death, and the benefits provided by section 212.

REGULATIONS

SEC. 215. [216] (a) The President shall from time to time prescribe regulations with respect to the appointment, promotion, retirement, termination of commission, title, pay, uniforms, allowances (including increased allowances for foreign service), and discipline of the commissioned corps of the Service.

(b) The Surgeon General, with the approval of the Secretary, unless specifically otherwise provided, shall promulgate all other regulations necessary to the administration of the Service, including regulations with respect to uniforms for employees, and regulations with respect to the custody, use, and preservation of the records, papers, and property of the Service.

(c) No regulations relating to qualifications for appointment of medical officers or employees shall give preference to any school of medicine.

USE OF SERVICE IN TIME OF WAR OR EMERGENCY

SEC. 216. [217] In time of war, or of emergency proclaimed by the President, he may utilize the Service to such extent and in such manner as shall in his judgment promote the public interest.

In time of war, or of emergency involving the national defense proclaimed by the President, he may by Executive order declare the commissioned corps of the Service to be a military service. Upon such declaration, and during the period of such war or such emergency or such part thereof as the President shall prescribe, the commissioned corps (a) shall constitute a branch of the land and naval forces of the United States, (b) shall, to the extent prescribed by regulations of the President, be subject to the Uniform Code of Military Justice, and (c) shall continue to operate as part of the Service except to the extent that the President may direct as Commander in Chief.

NATIONAL ADVISORY COUNCILS

SEC. 217. [218] (a) Within 120 days of the date of the enactment of this subsection, the Secretary shall appoint and organize a National Advisory Council on Migrant Health (hereinafter in this subsection referred to as the Council) which shall advise, consult with, and make recommendations to, the Secretary on matters concerning the organization, operation, selection, and funding of migrant health centers and other entities under grants and contracts under section 329.

(b) The Council shall consist of fifteen members, at least twelve of whom shall be members of the governing boards of migrant health centers or other entities assisted under section 329. Of such twelve members who are members of such governing boards, at least nine shall be chosen from among those members of such governing boards who are being served by such centers or grantees and who are familiar with the delivery of health care to migratory agricultural workers and seasonal agricultural workers. The remaining three Council members shall be individuals qualified by training and experience in the medical sciences or in the administration of health programs.

(c) Each member of the Council shall hold office for a term of four years, except that (1) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and (2) the terms of the members first taking office after the date of enactment of this subsection shall expire as follows: four shall expire four years after such date, four shall expire three years after such date, four shall expire two years after such date, and three shall expire one year after such date, as designated by the Secretary at the time of appointment.

(d) Section 14(a) of the Federal Advisory Committee Act shall not apply to the Council.

TRAINING OF OFFICERS

SEC. 218. [218a] (a) Appropriations available for the pay and allowances of commissioned officers of the Service shall also be available for the pay and allowances of any such officer on active duty while attending any Federal or non-Federal educational institution or training program and, subject to regulations of the President and to the limitation prescribed in such appropriations, for

payment of his tuition, fees, and other necessary expenses incident to such attendance.

(b) Any officer whose tuition, fees, and other necessary expenses are paid pursuant to subsection (a) while attending an educational institution or training program for a period in excess of thirty days shall be obligated to pay to the Service an amount equal to two times the total amount of such tuition, fees, and other necessary expenses received by such officer during such period, and two times the total amount of any compensation received by, and any allowance paid to, such officer during such period, if after return to active service such officer voluntarily leaves the Service within (1) six months, or (2) twice the period of such attendance, whichever is greater. Such subsequent period of service shall commence upon the cessation of such attendance and of any further continuous period of training duty for which no tuition and fees are paid by the Service and which is part of the officer's prescribed formal training program, whether such further training is at Service facility or otherwise. The Surgeon General may waive, in whole or in part, any payment which may be required by this subsection upon a determination that such payment would be inequitable or would not be in public interest.

ANNUAL AND SICK LEAVE

SEC. 219. [210-1] (a) In accordance with regulations of the President, commissioned officers of the Regular Corps and officers of the Reserve Corps on active duty may be granted annual leave and sick leave without any deductions from their pay and allowances: *Provided*, That such regulations shall not authorize annual leave to be accumulated in excess of sixty days.

(b) [Repealed.¹]

(c) Except in cases of emergency, no annual leave shall be granted to an officer described in subsection (a) of this section between the date upon which such officer applies for, or the Service directs, his retirement, separation, or release from active duty, whichever date is the earlier, and the effective date of such retirement, separation or release from active duty.

(d) For purposes of this section the term "accumulated annual leave" means unused accrued annual leave carried forward from one leave year into a succeeding leave year, and the term "accrued annual leave" means the annual leave accruing to an officer during one leave year.

PROMOTION CREDIT—ASSISTANT GRADE

SEC. 220. [211c] Any medical officer of the Regular Corps of the Public Health Service who—

(1)(A) was appointed to the assistant grade in the Regular Corps and whose service in such Corps has been continuous from the date of appointment or (B) may hereafter be appointed to the assistant grade in the Regular Corps, and

(2) had or will have completed a medical internship on the date of such appointment,

¹Superseded by section 503(b) of title 37, United States Code.

shall be credited with one year for purposes of promotion and seniority in grade, except that no such credit shall be authorized if the officer has received or will receive similar credit for his internship under other provisions of law. In the case of an officer on active duty on the effective date of this section who is entitled to the credit authorized herein, the one year shall be added to the promotion and seniority-in-grade credits with which he is credited on such date.

RIGHTS, PRIVILEGES, ETC. OF OFFICERS AND SURVIVING
BENEFICIARIES

SEC. 221. [213a] (a) Commissioned officers of the Service or their surviving beneficiaries are entitled to all the rights, benefits, privileges, and immunities now or hereafter provided for commissioned officers of the Army or their surviving beneficiaries under the following provisions of title 10, United States Code:

(1) Section 1036, Escorts for dependents of members: transportation and travel allowances.

(2) Chapter 61, Retirement or Separation for Physical Disability, except that sections 1201, 1202, and 1203 do not apply to commissioned officers of the Public Health Service who have been ordered to active duty for training for a period of more than 30 days.

(3) Chapter 69, Retired Grade, except sections 1370, 1374, 1375, and 1376(a).

(4) Chapter 71, Computation of Retired Pay, except formula No. 3 of section 1401.

(5) Chapter 73, Retired Serviceman's Family Protection Plan, Survivor Benefit Plan.

(6) Chapter 75, Death Benefits.

(7) Section 2771, Final settlement of accounts: deceased members.

(8) Chapter 163, Military Claims, but only when commissioned officers of the Service are entitled to military benefits under section 212 of this Act.

(9) Section 2603, Acceptance of fellowships, scholarships, or grants.

(10) Section 2634 Motor vehicles: for members on permanent change of station.

(11) Section 1035, Deposit of savings.

(12) Section 1552, Correction of military records: claims incident thereto.

(13) Section 1553, Review of discharge or dismissal.

(14) Section 1554, Review of retirement or separation without pay for physical disability.

(15) Section 1124, Cash awards for suggestions, inventions, or scientific achievements.

(b) The authority vested by title 10, United States Code, in the "military departments", "the Secretary concerned", or "the Secretary of Defense" with respect to the rights, privileges, immunities, and benefits referred to in subsection (a) shall be exercised, with respect to commissioned officers of the Service, by the Secretary of Health, Education, and Welfare or his designee.

ADVISORY COUNCILS OR COMMITTEES

SEC. 222. [217a] (a) The Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, from time to time, appoint such advisory councils or committees (in addition to those authorized to be established under other provisions of law), for such periods of time, as he deems desirable with such period commencing on a date specified by the Secretary for the purpose of advising him in connection with any of his functions.

(b) Members of any advisory council or committee appointed under this section who are not regular full-time employees of the United States shall, while attending meetings or conferences of such council or committee or otherwise engaged on business of such council or committee receive compensation and allowances as provided in section 208(c) for members of national advisory councils established under this Act.

(c) Upon appointment of any such council or committee, the Secretary may delegate to such council or committee such advisory functions relating to grants-in-aid for research or training projects or programs, in the areas or fields with which such council or committee is concerned, as the Secretary determines to be appropriate.

VOLUNTEER SERVICES

SEC. 223. [217b] Subject to regulations, volunteer and uncompensated services may be accepted by the Secretary, or by any other officer or employee of the Department of Health and Human Services designated by him, for use in the operation of any health care facility or in the provision of health care.

DEFENSE OF CERTAIN MALPRACTICE AND NEGLIGENCE SUITS

SEC. 224. [233] (a) The remedy against the United States provided by sections 1346(b) and 2672 of title 28, or by alternative benefits provided by the United States where the availability of such benefits precludes a remedy under section 1346(b) of title 28, for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigation, by any commissioned officer or employee of the Public Health Service while acting within the scope of his office or employment, shall be exclusive of any other civil action or proceeding by reason of the same subject-matter against the officer or employee (or his estate) whose act or omission gave rise to the claim.

(b) The Attorney General shall defend any civil action or proceeding brought in any court against any person referred to in subsection (a) of this section (or his estate) for any such damage or injury. Any such person against whom such civil action or proceeding is brought shall deliver within such time after date of service or knowledge of service as determined by the Attorney General, all process served upon him or an attested true copy thereof to his immediate superior or to whomever was designated by the Secretary

to receive such papers and such persons shall promptly furnish copies of the pleading and process therein to the United States attorney for the district embracing the place wherein the proceeding is brought, to the Attorney General, and to the Secretary.

(c) Upon a certification by the Attorney General that the defendant was acting in the scope of his employment at the time of the incident out of which the suit arose, any such civil action or proceeding commenced in a State court shall be removed without bond at any time before trial by the Attorney General to the district court of the United States of the district and division embracing the place wherein it is pending and the proceeding deemed a tort action brought against the United States under the provisions of title 28 and all references thereto. Should a United States district court determine on a hearing on a motion to remand held before a trial on the merit that the case so removed is one in which a remedy by suit within the meaning of subsection (a) of this section is not available against the United States, the case shall be remanded to the State Court: *Provided*, That where such a remedy is precluded because of the availability of a remedy through proceedings for compensation or other benefits from the United States as provided by any other law, the case shall be dismissed, but in the event the running of any limitation of time for commencing, or filing an application or claim in, such proceedings for compensation or other benefits shall be deemed to have been suspended during the pendency of the civil action or proceeding under this section.

(d) The Attorney General may compromise or settle any claim asserted in such civil action or proceeding in the manner provided in section 2677 of title 28 and with the same effect.

(e) For purposes of this section, the provisions of section 2680(h) of title 28 shall not apply to assault or battery arising out of negligence in the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigations.

(f) The Secretary or his designee may, to the extent that he deems appropriate, hold harmless or provide liability insurance for any officer or employee of the Public Health Service for damage for personal injury, including death, negligently caused by such officer or employee while acting within the scope of his office or employment and as a result of the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigations, if such employee is assigned to a foreign country or detailed to a State or political subdivision thereof or to a non-profit institution, and if the circumstances are such as are likely to preclude the remedies of third persons against the United States described in section 2679(b) of title 28, for such damage or injury.

(g)(1) For purposes of this section, an entity described in paragraph (4) and any officer, employee, or contractor (subject to paragraph (5)) of such an entity who is a physician or other licensed or certified health care practitioner shall be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer of the full amount estimated under subsection (k)(1)(A) was made under subsection (k)(3) (subject to paragraph (3)). The remedy against the United States for an entity described in paragraph (4) and any officer, employee,

or contractor (subject to paragraph (5)) of such an entity who is deemed to be an employee of the Public Health Service pursuant to this paragraph shall be exclusive of any other civil action or proceeding to the same extent as the remedy against the United States is exclusive pursuant to subsection (a).

(2) If, with respect to an entity or person deemed to be an employee for purposes of paragraph (1), a cause of action is instituted against the United States pursuant to this section, any claim of the entity or person for benefits under an insurance policy with respect to medical malpractice relating to such cause of action shall be subrogated to the United States.

(3) This subsection shall apply with respect to a cause of action arising from an act or omission which occurs on or after January 1, 1993. This subsection shall not apply with respect to a cause of action arising from an act or omission which occurs on or after January 1, 1996.

(4) An entity described in this paragraph is a public or non-profit private entity receiving Federal funds under any of the following grant programs:

(A) Section 329 (relating to grants for migrant health centers).

(B) Section 330 (relating to grants for community health centers).

(C) Section 340 (relating to grants for health services for the homeless).

(D) Section 340A (relating to grants for health services for residents of public housing).

(5) For purposes of paragraph (1), an individual may be considered a contractor of an entity described in paragraph (4) only if—

(A) the individual normally performs on average at least 32½ hours of service per week for the entity for the period of the contract; or

(B) in the case of an individual who normally performs on average less than 32½ hours of services per week for the entity for the period of the contract and is a licensed or certified provider of obstetrical services—

(i) the individual's medical malpractice liability insurance coverage does not extend to services performed by the individual for the entity under the contract, or

(ii) the Secretary finds that patients to whom the entity furnishes services will be deprived of obstetrical services if such individual is not considered a contractor of the entity for purposes of paragraph (1).

(h) Notwithstanding subsection (g)(1), the Secretary, in consultation with the Attorney General, may not deem an entity described in subsection (g)(4) to be an employee of the Public Health Service Act for purposes of this section unless the entity—

(1) has implemented appropriate policies and procedures to reduce the risk of malpractice and the risk of lawsuits arising out of any health or health-related functions performed by the entity;

(2) has reviewed and verified the professional credentials, references, claims history, fitness, professional review organization findings, and license status of its physicians and other

licensed or certified health care practitioners, and, where necessary, has obtained the permission from these individuals to gain access to this information;

(3) has no history of claims having been filed against the United States as a result of the application of this section to the entity or its officers, employees, or contractors as provided for under this section, or, if such a history exists, has fully cooperated with the Attorney General in defending against any such claims and either has taken, or will take, any necessary corrective steps to assure against such claims in the future; and

(4) has fully cooperated with the Attorney General in providing information relating to an estimate described under subsection (k).

(i)(1) Notwithstanding subsection (g)(1), the Attorney General, in consultation with the Secretary, may determine, after notice and opportunity for a hearing, that an individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of an entity described in subsection (g)(4) shall not be deemed to be an employee of the Public Health Service for purposes of this section, if treating such individual as such an employee would expose the Government to an unreasonably high degree of risk of loss because such individual—

(A) does not comply with the policies and procedures that the entity has implemented pursuant to subsection (h)(1);

(B) has a history of claims filed against him or her as provided for under this section that is outside the norm for licensed or certified health care practitioners within the same specialty;

(C) refused to reasonably cooperate with the Attorney General in defending against any such claim;

(D) provided false information relevant to the individual's performance of his or her duties to the Secretary, the Attorney General, or an applicant for or recipient of funds under this Act; or

(E) was the subject of disciplinary action taken by a State medical licensing authority or a State or national professional society.

(2) A final determination by the Attorney General under this subsection that an individual physician or other licensed or certified health care professional shall not be deemed to be an employee of the Public Health Service shall be effective upon receipt by the entity employing such individual of notice of such determination, and shall apply only to acts or omissions occurring after the date such notice is received.

(j) In the case of a health care provider who is an officer, employee, or contractor of an entity described in subsection (g)(4), section 335(e) shall apply with respect to the provider to the same extent and in the same manner as such section applies to any member of the National Health Service Corps.

(k)(1)(A) For each of the fiscal years 1993, 1994, and 1995, the Attorney General, in consultation with the Secretary, shall estimate by the beginning of the year (except that an estimate shall be made for fiscal year 1993 by December 31, 1992, subject to an

adjustment within 90 days thereafter) the amount of all claims which are expected to arise under this section (together with related fees and expenses of witnesses) for which payment is expected to be made in accordance with section 1346 and chapter 171 of title 28, United States Code, from the acts or omissions, during the calendar year that begins during that fiscal year, of entities described in subsection (g)(4) and of officers, employees, or contractors (subject to subsection (g)(5)) of such entities.

(B) The estimate under subparagraph (A) shall take into account—

(i) the value and frequency of all claims for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions by entities described in subsection (g)(4) or by officers, employees, or contractors (subject to subsection (g)(5)) of such entities who are deemed to be employees of the Public Health Service under subsection (g)(1) that, during the preceding 5-year period, are filed under this section or, with respect to years occurring before this subsection takes effect, are filed against persons other than the United States,

(ii) the amounts paid during that 5-year period on all claims described in clause (i), regardless of when such claims were filed, adjusted to reflect payments which would not be permitted under section 1346 and chapter 171 of title 28, United States Code, and

(iii) amounts in the fund established under paragraph (2) but unspent from prior fiscal years.

(2) Subject to appropriations, for each of the fiscal years 1993, 1994, and 1995, the Secretary shall establish a fund of an amount equal to the amount estimated under paragraph (1) that is attributable to entities receiving funds under each of the grant programs described in paragraph (4) of subsection (g), but not to exceed a total of \$30,000,000 for each such fiscal year. Appropriations for purposes of this paragraph shall be made separate from appropriations made for purposes of sections 329, 330, 340 and 340A.

(3) In order for payments to be made for judgments against the United States (together with related fees and expenses of witnesses) pursuant to this section arising from the acts or omissions of entities described in subsection (g)(4) and of officers, employees, or contractors (subject to subsection (g)(5)) of such entities, the total amount contained within the fund established by the Secretary under paragraph (2) for a fiscal year shall be transferred not later than the December 31 that occurs during the fiscal year to the appropriate accounts in the Treasury.

PUBLIC HEALTH AND NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP
TRAINING PROGRAM

SEC. 225. [Repealed.¹]

¹ Superseded by subpart III of part D of title III.

ADMINISTRATION OF GRANTS IN CERTAIN MULTIGRANT PROJECTS

SEC. 226. [235] For the purpose of facilitating the administration of, and expediting the carrying out of the purposes of, the programs established by titles VII, VIII, and IX, and sections 304, 314(a), 314(b), 314(c), 314(d), and 314(e) of this Act in situations in which grants are sought or made under two or more of such programs with respect to a single project, the Secretary is authorized to promulgate regulations—

(1) under which the administrative functions under such programs with respect to such project will be performed by a single administrative unit which is the administrative unit charged with the administration of any of such programs or is the administrative unit charged with the supervision of two or more of such programs;

(2) designed to reduce the number of applications, reports, and other materials required under such programs to be submitted with respect to such project, and otherwise to simplify, consolidate, and make uniform (to the extent feasible), the data and information required to be contained in such applications, reports, and other materials; and

(3) under which inconsistent or duplicative requirements imposed by such programs will be revised and made uniform with respect to such project;

except that nothing in this section shall be construed to authorize the Secretary to waive or suspend, with respect to any such project, any requirement with respect to any of such programs if such requirement is imposed by law or by any regulation required by law.

ORPHAN PRODUCTS BOARD

SEC. 227. [236] (a) There is established in the Department of Health and Human Services a board for the development of drugs (including biologics) and devices (including diagnostic products) for rare diseases or conditions to be known as the Orphan Products Board. The Board shall be comprised of the Assistant Secretary for Health of the Department of Health and Human Services and representatives, selected by the Secretary, of the Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control and Prevention, and any other Federal department or agency which the Secretary determines has activities relating to drugs and devices for rare diseases or conditions. The Assistant Secretary for Health shall chair the Board.

(b) The function of the Board shall be to promote the development of drugs and devices for rare diseases or conditions and the coordination among Federal, other public, and private agencies in carrying out their respective functions relating to the development of such articles, such diseases or conditions.

(c) In the case of drugs for rare diseases or conditions the Board shall—

(1) evaluate—

(A) the effect of subchapter B of the Federal Food, Drug, and Cosmetic Act on the development of such drugs, and

(B) the implementation of such subchapter;

(2) evaluate the activities of the National Institutes of Health for the development of drugs for such diseases or conditions,

(3) assure appropriate coordination among the Food and Drug Administration, the National Institutes of Health and the Centers for Disease Control and Prevention in the carrying out of their respective functions relating to the development of drugs for such diseases or conditions to assure that the activities of each agency are complementary.

(4) assure appropriate coordination among all interested Federal agencies, manufacturers, and organizations representing patients, in their activities relating to such drugs,

(5) with the consent of the sponsor of a drug for a rare disease or condition exempt under section 505(i) of the Federal Food, Drug, and Cosmetic Act or regulations issued under such section, inform physicians and the public respecting the availability of such drug for such disease or condition and inform physicians and the public respecting the availability of drugs approved under section 505(c) of such Act or licensed under section 351 of this Act for rare diseases or conditions,

(6) seek business entities and others to undertake the sponsorship of drugs for rare diseases or conditions, seek investigators to facilitate the development of such drugs, and seek business entities to participate in the distribution of such drugs, and

(7) recognize the efforts of public and private entities and individuals in seeking the development of drugs for rare diseases or conditions and in developing such drugs.

(d) The Board shall consult with interested persons respecting the activities of the Board under this section and as part of such consultation shall provide the opportunity for the submission of oral views.

(e) The Board shall submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report—

(1) identifying the drugs which have been designated under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition,

(2) describing the activities of the Board, and

(3) containing the results of the evaluations carried out by the Board.

The Director of the National Institutes of Health shall submit to the Board for inclusion in the annual report a report on the rare disease and condition research activities of the Institutes of the National Institutes of Health; the Secretary of the Treasury shall submit to the Board for inclusion in the annual report a report on the use of the credit against tax provided by section 44H of the Internal Revenue Code of 1954; and the Secretary of Health and Human Services shall submit to the Board for inclusion in the annual report a report on the program of assistance under section 5 of the Orphan Drug Act for the development of drugs for rare diseases and conditions. Each annual report shall be submitted by June 1 of each year for the preceding calendar year.

SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH SERVICE

SEC. 228. [237] (a)(1) There shall be in the Public Health Service a Silvio O. Conte Senior Biomedical Research Service, not to exceed 500 members.

(2) The authority established in paragraph (1) regarding the number of members in the Silvio O. Conte Senior Biomedical Research Service is in addition to any authority established regarding the number of members in the commissioned Regular Corps, in the Reserve Corps, and in the Senior Executive Service. Such paragraph may not be construed to require that the number of members in the commissioned Regular Corps, in the Reserve Corps, or in the Senior Executive Service be reduced to offset the number of members serving in the Silvio O. Conte Senior Biomedical Research Service (in this section referred to as the "Service").

(b) The Service shall be appointed by the Secretary without regard to the provisions of title 5, United States Code, regarding appointment, and shall consist of individuals outstanding in the field of biomedical research or clinical research evaluation. No individual may be appointed to the Service unless such individual (1) has earned a doctoral level degree in biomedicine or a related field, and (2) meets the qualification standards prescribed by the Office of Personnel Management for appointment to a position at GS-15 of the General Schedule. Notwithstanding any previous applicability to an individual who is a member of the Service, the provisions of subchapter I of chapter 35 (relating to retention preference), chapter 43 (relating to performance appraisal and performance actions), chapter 51 (relating to classification), subchapter III of chapter 53 (relating to General Schedule pay rates), and chapter 75 (relating to adverse actions) of title 5, United States Code, shall not apply to any member of the Service.

(c) The Secretary shall develop a performance appraisal system designed to—

(1) provide for the systematic appraisal of the performance of members, and

(2) encourage excellence in performance by members.

(d)(1) The Secretary shall determine, subject to the provisions of this subsection, the pay of members of the Service.

(2) The pay of a member of the Service shall not be less than the minimum rate payable for GS-15 of the General Schedule and shall not exceed the rate payable for level I of the Executive Schedule unless approved by the President under section 5377(d)(2) of title 5, United States Code.

(e) The Secretary may, upon the request of a member who—

(1) performed service in the employ of an institution of higher education immediately prior to his appointment as a member of the Service, and

(2) retains the right to continue to make contributions to the retirement system of such institution, contribute an amount not to exceed 10 percent per annum of the member's basic pay to such institution's retirement system on behalf of such member. A member who requests that such contribution be made shall not be covered by, or earn service credit under, any retirement system established for employees of the United

States under title 5, United States Code, but such service shall be creditable for determining years of service under section 6303(a) of such title.

(f) Subject to the following sentence, the Secretary may, notwithstanding the provisions of title 5, United States Code, regarding appointment, appoint an individual who is separated from the Service involuntarily and without cause to a position in the competitive civil service at GS-15 of the General Schedule, and such appointment shall be a career appointment. In the case of such an individual who immediately prior to his appointment to the Service was not a career appointee in the civil service or the Senior Executive Service, such appointment shall be in the excepted civil service and may not exceed a period of 2 years.

(g) The Secretary shall promulgate such rules and regulations, not inconsistent with this section, as may be necessary for the efficient administration of the Service.

PART B—MISCELLANEOUS PROVISIONS

GIFTS

SEC. 231. [238] (a) The Secretary is authorized to accept on behalf of the United States gifts made unconditionally by will or otherwise for the benefit of the Service or for the carrying out of any of its functions. Conditional gifts may be so accepted if recommended by the Surgeon General, and the principal of and income from any such conditional gift shall be held, invested, reinvested, and used in accordance with its conditions, but no gift shall be accepted which is conditioned upon any expenditure not to be met therefrom or from the income thereof unless such expenditure has been approved by Act of Congress.

(b) Any unconditional gift of money accepted, pursuant to the authority granted in subsection (a) of this section, the net proceeds from the liquidation (pursuant to subsection (c) or subsection (d) of this section) of any other property so accepted, and the proceeds of insurance on any such gift property not used for its restoration, shall be deposited in the Treasury of the United States and are hereby appropriated and shall be held in trust by the Secretary of the Treasury for the benefit of the Service, and he may invest and reinvest such funds in interest-bearing obligations of the United States or in obligations guaranteed as to both principal and interest by the United States. Such gifts and the income from such investments shall be available for expenditure in the operation of the Service and the performance of its functions, subject to the same examination and audit as is provided for appropriations made for the Service by Congress.

(c) The evidences of any unconditional gift of intangible personal property, other than money, accepted pursuant to the authority granted in subsection (a) of this section shall be deposited with the Secretary of the Treasury and he, in his discretion, may hold them, or liquidate them except that they shall be liquidated upon the request of the Secretary, whenever necessary to meet payments required in the operation of the Service or the performance of its functions. The proceeds and income from any such property held by

the Secretary of the Treasury shall be available for expenditure as is provided in subsection (b) of this section.

(d) The Secretary shall hold any real property or any tangible personal property accepted unconditionally pursuant to the authority granted in subsection (a) of this section and he shall permit such property to be used for the operation of the Service and the performance of its functions or he may lease or hire such property, and may insure such property, and deposit the income thereof with the Secretary of the Treasury to be available for expenditure as provided in subsection (b) of this section: *Provided*, That the income from any such real property or tangible personal property shall be available for expenditure in the discretion of the Secretary for the maintenance, preservation, or repair and insurance of such property and that any proceeds from insurance may be used to restore the property insured. Any such property when not required for the operation of the Service or the performance of its functions may be liquidated by the Secretary, and the proceeds thereof deposited with the Secretary of the Treasury, whenever in his judgment the purposes of the gifts will be served thereby.

USE OF IMMIGRATION STATION HOSPITALS

SEC. 232. [238a] The Immigration and Naturalization Service may, by agreement of the heads of the departments concerned, permit the Public Health Service to use hospitals at immigration stations for the care of Public Health Service patients. The Surgeon General shall reimburse the Immigration and Naturalization Service for the actual cost of furnishing fuel, light, water, telephone, and similar supplies and services, which reimbursement shall be covered into the proper Immigration and Naturalization Service appropriation, or such costs may be paid from working funds established as provided by law, but no charge shall be made for the expense of physical upkeep of the hospitals. The Immigration and Naturalization Service shall reimburse the Surgeon General for the care and treatment of persons detained in hospitals of the Public Health Service at the request of the Immigration and Naturalization Service unless such persons are entitled to care and treatment under section 322(a).¹

MONEY COLLECTED FOR CARE OF PATIENTS

SEC. 233. [238b] Money collected as provided by law for expenses incurred in the care and treatment of foreign seamen, and money received for the care and treatment of pay patients, including any amounts received from any executive department on account of care and treatment of pay patients, shall be covered into the appropriation from which the expenses of such care and treatment were paid.

¹ Subsection (a) of section 322 was repealed by section 986 of Public Law 97-35, and the Public Law redesignated former subsection (c) as subsection (a). Section 232 (above) was enacted before this repeal and redesignation. Current section 322(a) authorizes the treatment and care of certain persons. (Section 232 was originally enacted as section 502, and was subsequently redesignated by Public Laws 98-24, 99-660, 100-690, and 103-43.)

TRANSPORTATION OF REMAINS OF OFFICERS

SEC. 234. [238c] Appropriations available for traveling expenses of the Service shall be available for meeting the cost of preparation for burial and of transportation to the place of burial of remains of commissioned officers, and of personnel specified in regulations, who die in line of duty. Appropriations available for carrying out the provisions of this Act shall also be available for the payment of such expenses relating to the recovery, care, and disposition of the remains of personnel or their dependents as may be authorized under other provisions of law.

GRANTS TO FEDERAL INSTITUTIONS

SEC. 235. [238d] Appropriations to the Public Health Service available under this Act for research, training, or demonstration project grants or for grants to expand existing treatment and research programs and facilities for alcoholism, narcotic addiction, drug abuse, and drug dependence and appropriations under title VI of the Mental Health Systems Act shall also be available, on the same terms and conditions as apply to non-Federal institutions, for grants for the same purpose to Federal institutions, except that grants to such Federal institutions may be funded at 100 per centum of the costs.

TRANSFER OF FUNDS

SEC. 236. [238e] For the purpose of any reorganization under section 202, the Secretary, with the approval of the Director of the Bureau of the Budget,¹ is authorized to make such transfers of funds between appropriations as may be necessary for the continuance of transferred functions.

AVAILABILITY OF APPROPRIATIONS

SEC. 237. [238f] Appropriations for carrying out the purposes of this Act shall be available for expenditure for personal services and rent at the seat of Government; books of reference, periodicals, and exhibits; printing and binding; transporting in Government-owned automotive equipment, to and from school, children of personnel who have quarters for themselves and their families at stations determined by the Surgeon General to be isolated stations; expenses incurred in pursuing, identifying, and returning prisoners who escape from any hospital, institution, or station of the Service or from the custody of any officer or employee of the Service, including rewards for the capture of such prisoners; furnishing, repairing, and cleaning such wearing apparel as may be prescribed by the Surgeon General for use by employees in the performance of their official duties; reimbursing officers and employees, subject to regulations of the Secretary, for the cost of repairing or replacing their personal belongings damaged or destroyed by patients while such officers or employees are engaged in the performance of their official duties; and maintenance of buildings of the National Institutes of Health.

¹ Now the Office of Management and Budget.

UNAUTHORIZED WEARING OF UNIFORMS

SEC. 238. [238g] Except as may be authorized by regulations of the President, the insignia and uniform of commissioned officers of the Service, or any distinctive part of such insignia or uniform, or any insignia or uniform any part of which is similar to a distinctive part thereof, shall not be worn, after the promulgation of such regulations, by any person other than a commissioned officer of the Service.

ANNUAL REPORT

SEC. 239. [238h] The Surgeon General shall transmit to the Secretary, for submission to the Congress at the beginning of each regular session, a full report of the administration of the functions of the Service under this Act, including a detailed statement of receipts and disbursements.

MEMORIALS AND OTHER ACKNOWLEDGMENTS

SEC. 240. [238i] The Secretary may provide for suitably acknowledging, within the Department (whether by memorials, designations, or other suitable acknowledgments), (1) efforts of persons who have contributed substantially to the health of the Nation and (2) gifts for use in activities of the Department related to health.

EVALUATION OF PROGRAMS

SEC. 241. [238j] (a) IN GENERAL.—Such portion as the Secretary shall determine, but not less than 0.2 percent nor more than 1 percent, of any amounts appropriated for programs authorized under this Act shall be made available for the evaluation (directly, or by grants of contracts) of the implementation and effectiveness of such programs.

(b) REPORT ON EVALUATIONS.—Not later than February 1 of each year, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report summarizing the findings of the evaluations conducted under subsection (a).

CONTRACT AUTHORITY

SEC. 242. [238k] The authority of the Secretary to enter into contracts under this Act shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

RECOVERY

SEC. 243. [238l] (a) If any facility with respect to which funds have been paid under the Community Mental Health Centers Act (as such Act was in effect prior to October 1, 1981) is, at any time within twenty years after the completion of remodeling, construction, or expansion or after the date of its acquisition—

(1) sold or transferred to any entity (A) which would not have been qualified to file an application under section 222 of

such Act (as such section was in effect prior to October 1, 1981) or (B) which is disapproved as a transferee by the State mental health agency or by another entity designated by the chief executive officer of the State, or

(2) ceases to be used by a community mental health center in the provision of comprehensive mental health services, the United States shall be entitled to recover from the transferor, transferee, or owner of the facility, the base amount prescribed by subsection (c)(1) plus the interest (if any) prescribed by subsection (c)(2).

(b) The transferor and transferee of a facility that is sold or transferred as described in subsection (a)(1), or the owner of a facility the use of which changes as described in subsection (a)(2), shall provide the Secretary written notice of such sale, transfer, or change within 10 days after the date on which such sale, transfer, or cessation of use occurs or within 30 days after the date of enactment of this subsection, whichever is later.

(c)(1) The base amount that the United States is entitled to recover under subsection (a) is the amount bearing the same ratio to the then value (as determined by the agreement of the parties or in an action brought in the district court of the United States for the district in which the facility is situated) of so much of the facility as constituted an approved project or projects as the amount of the Federal participation bore to the cost of the remodeling, construction, expansion, or acquisition of the project or projects.

(2)(A) The interest that the United States is entitled to recover under subsection (a) is the interest for the period (if any) described in subparagraph (B) at a rate (determined by the Secretary) based on the average of the bond equivalent rates of ninety-one-day Treasury bills auctioned during that period.

(B) The period referred to in subparagraph (A) is the period beginning—

(i) if notice is provided as prescribed by subsection (b), 191 days after the date on which such sale, transfer, or cessation of use occurs, or

(ii) if notice is not provided as prescribed by subsection (b), 11 days after such sale, transfer, or cessation of use occurs, and ending on the date the amount the United States is entitled to recover is collected.

(d) The Secretary may waive the recovery rights of the United States under subsection (a) with respect to a facility (under such conditions as the Secretary may establish by regulation) if the Secretary determines that there is good cause for waiving such rights.

(e) The right of recovery of the United States under subsection (a) shall not, prior to judgment, constitute a lien on any facility.

USE OF FISCAL AGENTS

SEC. 244. [238m] (a) The Secretary may enter into contracts with fiscal agents—

(1)(A) to determine the amounts payable to persons who, on behalf of the Indian Health Service, furnish health services to eligible Indians,

(B) to determine the amounts payable to persons who, on behalf of the Public Health Service, furnish health services to individuals pursuant to section 319 or 322,

(2) to receive, disburse, and account for funds in making payments described in paragraph (1),

(3) to make such audits of records as may be necessary to assure that these payments are proper, and

(4) to perform such additional functions as may be necessary to carry out the functions described in paragraphs (1) through (3).

(b)(1) Contracts under subsection (a) may be entered into without regard to section 3709 of the Revised Statutes (41 U.S.C. 5) or any other provision of law requiring competition.

(2) No such contract shall be entered into with an entity unless the Secretary finds that the entity will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, and other matters as he finds pertinent.

(c) A contract under subsection (a) may provide for advances of funds to enable entities to make payments under the contract.

(d) Subsections (d) and (e) of section 1842 of the Social Security Act shall apply to contracts with entities under subsection (a) in the same manner as they apply to contracts with carriers under that section.

(e) In this section, the term "fiscal agent" means a carrier described in section 1842(f)(1) of the Social Security Act and includes, with respect to contracts under subsection (a)(1)(A), an Indian tribe or tribal organization acting under contract with the Secretary under the Indian Self-Determination Act (Public Law 93-638).

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

IN GENERAL

SEC. 301. [241] (a) The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to—

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under title 10, United States Code, sections 2353 and 2354, except that determination, approval, and certification required thereby shall be by the Secretary of Health, Education, and Welfare; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b)(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health, Education, and Welfare and shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains—

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient,

or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved—

(I) from a Federal agency outside the Department of Health, Education, and Welfare for the Secretary, or

(II) from an entity within the Department of Health, Education, and Welfare to any other entity within the Department,

to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in Appropriation Acts.

(c) The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

NARCOTICS

SEC. 302. [242] (a) In carrying out the purposes of section 301 with respect to drugs the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, and other drugs subject to control under the Controlled Substances Act and Controlled Substances Import and Export Act, together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary

to supply the normal and emergency medicinal and scientific requirements of the United States, shall be reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts.

(b) The Surgeon General shall cooperate with States for the purpose of aiding them to solve their narcotic drug problems and shall give authorized representatives of the States the benefit of his experience in the care, treatment, and rehabilitation of narcotic addicts to the end that each State may be encouraged to provide adequate facilities and methods for the care and treatment of its narcotic addicts.

MENTAL HEALTH

SEC. 303. [242a] (a) In carrying out the purposes of section 301 with respect to mental health—

(1) the Secretary, acting through the Director of the Center for Mental Health Services, is authorized to provide clinical training and instruction and to establish and maintain clinical traineeships (with such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the trainees as the Secretary may deem necessary);

(2) the Surgeon General¹ is authorized to make grants to State or local agencies, laboratories, and other public or non-profit agencies and institutions, and to individuals for investigations, experiments, demonstrations, studies, and research projects with respect to the development of improved methods of diagnosing mental illness, and of care, treatment, and rehabilitation of the mentally ill, including grants to State agencies responsible for administration of State institutions for care, or care and treatment, of mentally ill persons for developing and establishing improved methods of operations and administration of such institutions.

(b)² Nothing in the Single Convention on Narcotic Drugs, the Convention on Psychotropic Substances, or other treaties or international agreements shall be construed to limit, modify, or prevent the protection of the confidentiality of patient records or of the names and other identifying characteristics of research subjects as provided by any Federal, State, or local law or regulation.

(c) The Secretary may provide for training instruction, and traineeships under subsection (a)(1) through grants to public and other nonprofit institutions. Grants under paragraph (2) of subsection (a) may be made only upon recommendation of the National Advisory Mental Health Council. Such grants may be paid in advance or by way of reimbursement, as may be determined by the Surgeon General; and shall be made on such conditions as the Surgeon General finds necessary.

(d)(1) Any individual who has received a clinical traineeship, in psychology, psychiatry, nursing, marital and family therapy, or so-

¹Section 115(b) of Public Law 102-321 (106 Stat. 348) added the reference to the Surgeon General. See note on page 1 regarding the transfer of the authority of the Surgeon General.

²Subsection (b) became effective on July 15, 1980, the date on which the Convention on Psychotropic Substances, signed at Vienna, Austria on February 21, 1971, became effective with respect to the United States. See section 112 of Public Law 95-633.

cial work, under subsection (a)(1) that was not of a limited duration or experimental nature (as determined by the Secretary) is obligated to serve, in service determined by the Secretary to be appropriate in the light of the individual's training and experience, at the rate of one year for each year (or academic year, whichever the Secretary determines to be appropriate) of the traineeship.

(2) The service required under paragraph (1) shall be performed—

(A) for a public inpatient mental institution providing inpatient care or any entity receiving a grant under the Mental Health Systems Act,

(B) in a health health professional shortage area (as determined under subpart II of part D of this title),

(C) in any other area or for any other entity designated by the Secretary, or

(D) in a Federal or State correctional facility,

and shall begin within such period after the termination of the traineeship as the Secretary may determine. In developing criteria for determining for which institutions or entities or in which areas, referred to in the preceding sentence, individuals must perform service under paragraph (1), the Secretary shall give preference to institutions, entities, or areas which in his judgment have the greatest need for personnel to perform that service. The Secretary may permit service for or in other institutions, entities, or areas if the Secretary determines that the request for such service is supported by good cause.

(3) Any individual who fails to perform the service required under this subsection within the period prescribed by the Secretary is obligated to repay to the United States an amount equal to three times the cost of the traineeship (including stipends and allowances) plus interest at the maximum legal rate at the time of payment of the traineeship, multiplied, in any case in which the service so required has been performed in part, by the percentage which the length of the service not so performed is of the length of the service so required to be performed.

(4)(A) In the case of any individual any part of whose obligation to perform service under this subsection exists at the same time as any part of the individual's obligation to perform service under section 338C or 338D (because of receipt of a scholarship under subpart II of part D) or the individual's obligation to perform service under section 472¹ (because of receipt of a National Research Service Award), or both, the same service may not be used to any extent to meet more than one of those obligations.

(B) In any case to which subparagraph (A) is applicable and in which one of the obligations is to perform service under section 338C or 338D, the obligation to perform service under that section must be met (by performance of the required service or payment of damages) before the obligation to perform service under this subsection or under section 472.¹

¹Probably should be "section 487". (Section 472 concerns grants for training in medical library sciences.) Section 2 of Public Law 99-158 generally amended title IV of this Act, and under such amendments, provisions formerly contained in section 472 were restated in section 487.

(C) In any case to which subparagraph (A) is applicable, if any part of the obligation to perform service under section 472¹ exists at the same time as any part of the obligation to perform service under this subsection, the manner and time of meeting each obligation shall be prescribed by the Secretary.

(5) In disseminating application forms to individuals desiring traineeships, the Secretary shall include with such forms a fair summary of the liabilities under this subsection of an individual who receives a traineeship.

GENERAL AUTHORITY RESPECTING RESEARCH, EVALUATIONS, AND
DEMONSTRATIONS IN HEALTH STATISTICS, HEALTH SERVICES, AND
HEALTH CARE TECHNOLOGY ASSESSMENT

SEC. 304. [242b] (a) The Secretary may, through the Agency for Health Care Policy and Research or the National Center for Health Statistics or using National Research Service Awards or other appropriate authorities, undertake and support training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, evaluation, and demonstration projects set forth in section 306 and in title IX.

(b) To implement subsection (a) and section 306, the Secretary may, in addition to any other authority which under other provisions of this Act or any other law may be used by him to implement such subsection, do the following:

(1) Utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, provide technical assistance and advice, make grants to public and nonprofit private entities and individuals, and, when appropriate, enter into contracts with public and private entities and individuals.

(2) Admit and treat at hospitals and other facilities of the Service persons not otherwise eligible for admission and treatment at such facilities.

(3) Secure, from time to time and for such periods as the Secretary deems advisable but in accordance with section 3109 of title 5, United States Code, the assistance and advice of consultants from the United States or abroad. The Secretary may for the purpose of carrying out the functions set forth in sections 305,² 306, and 309, obtain (in accordance with section 3109 of title 5 of the United States Code, but without regard to the limitation in such section on the number of days or the period of service) for each of the centers the services of not more than fifteen experts who have appropriate scientific or professional qualifications.

(4) Acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary; and acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease

¹ See footnote 1 on page 47.

² See footnote 1 on page 49.

or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia.

(c)(1) The Secretary shall coordinate all health services research, evaluations, and demonstrations, all health statistical and epidemiological activities, and all research, evaluations, and demonstrations respecting the assessment of health care technology undertaken and supported through units of the Department of Health and Human Services. To the maximum extent feasible such coordination shall be carried out through the Agency for Health Care Policy and Research and the National Center for Health Statistics.

(2) The Secretary shall coordinate the health services research, evaluations, and demonstrations, the health statistical and (where appropriate) epidemiological activities, and the research, evaluations, and demonstrations respecting the assessment of health care technology authorized by this Act through the Agency for Health Care Policy and Research and the National Center for Health Statistics.

NATIONAL CENTER FOR HEALTH STATISTICS

SEC. 306.¹ [242k] (a) There is established in the Department of Health and Human Services the National Center for Health Statistics (hereinafter in this section referred to as the "Center") which shall be under the direction of a Director who shall be appointed by the Secretary. The Secretary, acting through the Center, shall conduct and support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

(b) In carrying out subsection (a), the Secretary, acting through the Center—

(1) shall collect statistics on—

(A) the extent and nature of illness and disability of the population of the United States (or of any groupings of the people included in the population), including life expectancy, the incidence of various acute and chronic illnesses, and infant and maternal morbidity and mortality,

(B) the impact of illness and disability of the population on the economy of the United States and on other aspects of the well-being of its population (or of such groupings),

(C) environmental, social, and other health hazards,

(D) determinants of health,

(E) health resources, including physicians, dentists, nurses, and other health professionals by specialty and type of practice and the supply of services by hospitals, extended care facilities, home health agencies, and other health institutions,

(F) utilization of health care, including utilization of (i) ambulatory health services by specialties and types of practice of the health professionals providing such serv-

¹Section 305, which established the National Center for Health Services Research and Health Care Technology Assessment, was repealed by section 6103(d)(1)(A) of Public Law 101-239 (103 Stat. 2205). Section 305 is superseded by title IX, which establishes an Agency for Health Care Policy and Research. See section 901(a).

ices, and (ii) services of hospitals, extended care facilities, home health agencies, and other institutions,

(G) health care costs and financing, including the trends in health care prices and cost, the sources of payments for health care services, and Federal, State, and local governmental expenditures for health care services, and

(H) family formation, growth, and dissolution;

(2) shall undertake and support (by grant or contract) research, demonstrations, and evaluations respecting new or improved methods for obtaining current data on the matters referred to in paragraph (1);

(3) may undertake and support (by grant or contract) epidemiological research, demonstrations, and evaluations on the matters referred to in paragraph (1); and

(4) may collect, furnish, tabulate, and analyze statistics, and prepare studies, on matters referred to in paragraph (1) upon request of public and nonprofit private entities under arrangements under which the entities will pay the cost of the service provided.

Amounts appropriated to the Secretary from payments made under arrangements made under paragraph (4) shall be available to the Secretary for obligation until expended.

(c) The Center shall furnish such special statistical and epidemiological compilations and surveys as the Committee on Labor and Human Resources and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives may request. Such statistical and epidemiological compilations and surveys shall not be made subject to the payment of the actual or estimated cost of the preparation of such compilations and surveys.

(d) To insure comparability and reliability of health statistics, the Secretary shall, through the Center, provide adequate technical assistance to assist State and local jurisdictions in the development of model laws dealing with issues of confidentiality and comparability of data.

(e) For the purpose of producing comparable and uniform health information and statistics, there is established the Cooperative Health Statistics System. The Secretary, acting through the Center, shall—

(1) coordinate the activities of Federal agencies involved in the design and implementation of the System;

(2) undertake and support (by grant or contract) research, development, demonstrations, and evaluations respecting the System;

(3) make grants to and enter into contracts with State and local health agencies to assist them in meeting the costs of data collection and other activities carried out under the System; and

(4) review the statistical activities of the Department of Health and Human Services to assure that they are consistent with the System.

States participating in the System shall designate a State agency to administer or be responsible for the administration of the statis-

tical activities within the State under the System. The Secretary, acting through the Center, shall prescribe guidelines to assure that statistical activities within States participating in the system produce uniform and timely data and assure appropriate access to such data.

(f) To assist in carrying out this section, the Secretary, acting through the Center, shall cooperate and consult with the Departments of Commerce and Labor and any other interested Federal departments or agencies and with State and local health departments and agencies. For such purpose he shall utilize insofar as possible the services or facilities of any agency of the Federal Government and, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5), of any appropriate State or other public agency, and may, without regard to such section, utilize the services or facilities of any private agency, organization, group, or individual, in accordance with written agreements between the head of such agency, organization, or group and the Secretary or between such individual and the Secretary. Payment, if any, for such services or facilities shall be made in such amounts as may be provided in such agreement.

(g) To secure uniformity in the registration and collection of mortality, morbidity, and other health data, the Secretary shall prepare and distribute suitable and necessary forms for the collection and compilation of such data.

(h)(1) There shall be an annual collection of data from the records of births, deaths, marriages, and divorces in registration areas. The data shall be obtained only from and restricted to such records of the States and municipalities which the Secretary, in his discretion, determines possess records affording satisfactory data in necessary detail and form. The Secretary shall encourage States and registration areas to obtain detailed data on ethnic and racial populations, including subpopulations of Hispanics, Asian Americans, and Pacific Islanders with significant representation in the State or registration area. Each State or registration area shall be paid by the Secretary the Federal share of its reasonable costs (as determined by the Secretary) for collecting and transcribing (at the request of the Secretary and by whatever method authorized by him) its records for such data.

(2) There shall be an annual collection of data from a statistically valid sample concerning the general health, illness, and disability status of the civilian noninstitutionalized population. Specific topics to be addressed under this paragraph, on an annual or periodic basis, shall include the incidence of illness and accidental injuries, prevalence of chronic diseases and impairments, disability, physician visits, hospitalizations, and the relationship between demographic and socioeconomic characteristics and health characteristics.

(i) The Center may provide to public and nonprofit private entities technical assistance in the effective use in such activities of statistics collected or compiled by the Center.

(j) In carrying out the requirements of section 304(c) and paragraph (1) of subsection (e) of this section, the Secretary shall coordinate health statistical and epidemiological activities of the Department of Health and Human Services by—

(1) establishing standardized means for the collection of health information and statistics under laws administered by the Secretary;

(2) developing, in consultation with the National Committee on Vital and Health Statistics, and maintaining the minimum sets of data needed on a continuing basis to fulfill the collection requirements of subsection (b)(1);

(3) after consultation with the National Committee on Vital and Health Statistics, establishing standards to assure the quality of health statistical and epidemiological data collection, processing, and analysis;

(4) in the case of proposed health data collections of the Department which are required to be reviewed by the Director of the Office of Management and Budget under section 3509 of title 44, United States Code, reviewing such proposed collections to determine whether they conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (2) and (3), and if any such proposed collection is found not to be in conformance, by taking such action as may be necessary to assure that it will conform to such sets of data and standards, and

(5) periodically reviewing ongoing health data collections of the Department, subject to review under such section 3509, to determine if the collections are being conducted in accordance with the minimum sets of data and the standards promulgated pursuant to paragraphs (2) and (3) and, if any such collection is found not to be in conformance, by taking such action as may be necessary to assure that the collection will conform to such sets of data and standards not later than the nineteenth day after the date of the completion of the review of the collection.

(k)(1) There is established in the Office of the Secretary a committee to be known as the National Committee on Vital and Health Statistics (hereinafter in this subsection, referred to as the "Committee") which shall consist of 16 members.

(2) The members of the Committee shall be appointed by the Secretary from among persons who have distinguished themselves in the fields of health statistics, health planning, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of 4 years.

(3) Members of the Committee shall be compensated in accordance with section 208(c).

(4) It shall be the function of the Committee to assist and advise the Secretary—

(A) to delineate statistical problems bearing on health and health services which are of national or international interest;

(B) to stimulate studies of such problems by other organizations and agencies whenever possible or to make investigations of such problems through subcommittees;

(C) to determine, approve, and revise the terms, definitions, classifications, and guidelines for assessing health status and health services, their distribution and costs, for use (i) within the Department of Health and Human Services, (ii) by all programs administered or funded by the Secretary, includ-

ing the Federal-State-local cooperative health statistics system referred to in subsection (e), and (iii) to the extent possible as determined by the head of the agency involved, by the Department of Veterans Affairs, the Department of Defense, and other Federal agencies concerned with health and health services;

(D) with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within the Department of Health and Human Services, with respect to the Cooperative Health Statistics System established under subsection (e), and with respect to the standardized means for the collection of health information and statistics to be established by the Secretary under subsection (j)(1);

(E) to review and comment on findings and proposals developed by other organizations and agencies and to make recommendations for their adoption or implementation by local, State, national, or international agencies;

(F) to cooperate with national committees of other countries and with the World Health Organization and other national agencies in the studies of problems of mutual interest; and

(G) to issue an annual report on the state of the Nation's health, its health services, their costs and distributions, and to make proposals for improvement of the Nation's health statistics and health information systems.

(5) In carrying out health statistical activities under this part, the Secretary shall consult with, and seek the advice of, the Committee and other appropriate professional advisory groups.

(1) In carrying out this section, the Secretary, acting through the Center, shall collect and analyze adequate health data that is specific to particular ethnic and racial populations, including data collected under national health surveys. Activities carried out under this subsection shall be in addition to any activities carried out under subsection (m).

(m)(1) The Secretary, acting through the Center, may make grants to public and nonprofit private entities for—

(A) the conduct of special surveys or studies on the health of ethnic and racial populations or subpopulations;

(B) analysis of data on ethnic and racial populations and subpopulations; and

(C) research on improving methods for developing statistics on ethnic and racial populations and subpopulations.

(2) The Secretary, acting through the Center, may provide technical assistance, standards, and methodologies to grantees supported by this subsection in order to maximize the data quality and comparability with other studies.

(3) Provisions of section 308(d) do not apply to surveys or studies conducted by grantees under this subsection unless the Secretary, in accordance with regulations the Secretary may issue, determines that such provisions are necessary for the conduct of the survey or study and receives adequate assurance that the grantee will enforce such provisions.

(n)(1) For health statistical and epidemiological activities undertaken or supported under subsections (a) through (l), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1998.

(2) For activities authorized in subsection (m), there are authorized to be appropriated \$5,000,000 for fiscal year 1991, \$7,500,000 for fiscal year 1992, \$10,000,000 for fiscal year 1993, and \$10,000,000 for each of the fiscal years 1994 through 1998. Of such amounts, the Secretary shall use not more than 10 percent for administration and for activities described in subsection (m)(2).

INTERNATIONAL COOPERATION

SEC. 307. [242l] (a) For the purpose of advancing the status of the health sciences in the United States (and thereby the health of the American people), the Secretary may participate with other countries in cooperative endeavors in biomedical research, health care technology, and the health services research and statistical activities authorized by section 306 and by title IX.

(b) In connection with the cooperative endeavors authorized by subsection (a), the Secretary may—

(1) make such use of resources offered by participating foreign countries as he may find necessary and appropriate;

(2) establish and maintain fellowships in the United States and in participating foreign countries;

(3) make grants to public institutions or agencies and to nonprofit private institutions or agencies in the United States and in participating foreign countries for the purpose of establishing and maintaining the fellowships authorized by paragraph (2);

(4) make grants or loans of equipment and materials, for use by public or nonprofit private institutions or agencies, or by individuals, in participating foreign countries;

(5) participate and otherwise cooperate in any international meetings, conferences, or other activities concerned with biomedical research, health services research, health statistics, or health care technology;

(6) facilitate the interchange between the United States and participating foreign countries, and among participating foreign countries, of research scientists and experts who are engaged in experiments or programs of biomedical research, health services research, health statistical activities, or health care technology activities, and in carrying out such purpose may pay per diem compensation, subsistence, and travel for such scientists and experts when away from their places of residence at rates not to exceed those provided in section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently;

(7) procure, in accordance with section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants; and

The Secretary may not, in the exercise of his authority under this section, provide financial assistance for the construction of any facility in any foreign country.

(8) enter into contracts with individuals for the provision of services (as defined in section 104 of part 37 of title 48, Code of Federal Regulations (48 CFR 37.104)) in participating foreign countries, which individuals may not be deemed employees of the United States for any purpose.¹

(c) The Secretary may provide to personnel appointed or assigned by the Secretary to serve abroad, allowances and benefits similar to those provided under chapter 9 of title I of the Foreign Service Act of 1990 (22 U.S.C. 4081 et seq.). Leaves of absence for personnel under this subsection shall be on the same basis as that provided under subchapter I of chapter 63 of title 5, United States Code, to individuals serving in the Foreign Service.

GENERAL PROVISIONS RESPECTING EFFECTIVENESS, EFFICIENCY, AND
QUALITY OF HEALTH SERVICES

SEC. 308. [242m] (a)(1) Not later than March 15 of each year, the Secretary shall submit to the President and Congress the following reports:

(A) A report on health care costs and financing. Such report shall include a description and analysis of the statistics collected under section 306(b)(1)(G).

(B) A report on health resources. Such report shall include a description and analysis, by geographical area, of the statistics collected under section 306(b)(1)(E).

(C) A report on the utilization of health resources. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 306(b)(1)(F).

(D) A report on the health of the Nation's people. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 306(b)(1)(A).

(2) The reports required in paragraph (1) shall be prepared through the National Center for Health Statistics.

(3) The Office of Management and Budget may review any report required by paragraph (1) of this subsection before its submission to Congress, but the Office may not revise any such report or delay its submission beyond the date prescribed for its submission, and may submit to Congress its comments respecting any such report.

(b)(1) No grant or contract may be made under section 304, 306, or 307 unless an application therefor has been submitted to the Secretary in such form and manner, and containing such information, as the Secretary may by regulation prescribe and unless a peer review group referred to in paragraph (2) has recommended the application for approval.

(2)(A) Each application submitted for a grant or contract under section 306 in an amount exceeding \$50,000 of direct costs and for a health services research, evaluation, or demonstration project, or for a grant under section 306(n), shall be submitted to a peer re-

¹ So in law. Section 310 of Public Law 102-531 (106 Stat. 3503) amended subsection (b) by adding a paragraph (8) at the end. The paragraph probably should have been inserted after paragraph (7).

view group for an evaluation of the technical and scientific merits of the proposals made in each such application. The Director of the National Center for Health Statistics shall establish such peer review groups as may be necessary to provide for such an evaluation of each such application.

(B) A peer review group to which an application is submitted pursuant to subparagraph (A) shall report its finding and recommendations respecting the application to the Secretary, acting through the Director of the National Center for Health Statistics, in such form and manner as the Secretary shall by regulation prescribe. The Secretary may not approve an application described in such subparagraph unless a peer review group has recommended the application for approval.

(C) The Secretary, acting through the Director of the National Center for Health Statistics, shall make appointments to the peer review groups required in subparagraph (A) from among persons who are not officers or employees of the United States and who possess appropriate technical and scientific qualifications, except that peer review groups regarding grants under section 306(n) may include appropriately qualified such officers and employees.

(c) The Secretary shall take such action as may be necessary to assure that statistics developed under sections 304 and 306 are of high quality, timely, comprehensive as well as specific, standardized, and adequately analyzed and indexed, and shall publish, make available, and disseminate such statistics on as wide a basis as is practicable.

(d) No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section 304, 306, or 307 may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and in the case of information obtained in the course of health statistical or epidemiological activities under section 304 or 306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(e)(1) Payments of any grant or under any contract under section 304, 306, or 307 may be made in advance or by way of reimbursement, and in such installments and on such conditions, as the Secretary deems necessary to carry out the purposes of such section.

(2) The amounts otherwise payable to any person under a grant or contract made under section 304, 306, or 307 shall be reduced by—

(A) amounts equal to the fair market value of any equipment or supplies furnished to such person by the Secretary for the purpose of carrying out the project with respect to which such grant or contract is made, and

(B) amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the Govern-

ment in connection with such project, if such officer or employee was assigned or detailed by the Secretary to perform such services,

but only if such person requested the Secretary to furnish such equipment or supplies, or such services, as the case may be.

(f) Contracts may be entered into under section 304 or 306 without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5).

HEALTH CONFERENCES AND HEALTH EDUCATION INFORMATION

SEC. 310. ¹ [242n] (a) A conference of the health authorities in and among the several States shall be called annually by the Secretary. Whenever in his opinion the interests of the public health would be promoted by a conference, the Secretary may invite as many of such health authorities and officials of other State or local public or private agencies, institutions, or organizations to confer as he deems necessary or proper. Upon the application of health authorities of five or more States it shall be the duty of the Secretary to call a conference of all State health authorities joining in the request. Each State represented at any conference shall be entitled to a single vote. Whenever at any such conference matters relating to mental health are to be discussed, the mental health authorities of the respective States shall be invited to attend.

(b) From time to time the Secretary shall issue information related to public health, in the form of publications or otherwise, for the use of the public, and shall publish weekly reports of health conditions in the United States and other countries and other pertinent health information for the use of persons and institutions concerned with health services.

PART B—FEDERAL-STATE COOPERATION

IN GENERAL

SEC. 311. [243] (a) The Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this Act which such authorities may be able and willing to provide. The Secretary shall also assist States and their political subdivisions in the prevention and suppression of communicable diseases and with respect to other public health matters, shall cooperate with and aid State and local authorities in the enforcement of their quarantine and other health regulations, and shall advise the several States on matters relating to the preservation and improvement of the public health.

(b) The Secretary shall encourage cooperative activities between the States with respect to comprehensive and continuing planning as to their current and future health needs, the establishment and maintenance of adequate public health services, and otherwise carrying out the public health activities. The Secretary is also authorized to train personnel for State and local health work. The Secretary may charge only private entities reasonable fees for the training of their personnel under the preceding sentence.

¹ Section 309, which provided for a council on health care technology, was repealed by section 6103(d)(1)(B) of Public Law 101-239 (103 Stat. 2205).

(c)(1) The Secretary is authorized to develop (and may take such action as may be necessary to implement) a plan under which personnel, equipment, medical supplies, and other resources of the Service and other agencies under the jurisdiction of the Secretary may be effectively used to control epidemics of any disease or condition and to meet other health emergencies or problems. The Secretary may enter into agreements providing for the cooperative planning between the Service and public and private community health programs and agencies to cope with health problems (including epidemics and health emergencies).

(2) The Secretary may, at the request of the appropriate State or local authority, extend temporary (not in excess of six months) assistance to States or localities in meeting health emergencies of such a nature as to warrant Federal assistance. The Secretary may require such reimbursement of the United States for assistance provided under this paragraph as he may determine to be reasonable under the circumstances. Any reimbursement so paid shall be credited to the applicable appropriation for the Service for the year in which such reimbursement is received.

GRANTS FOR COMPREHENSIVE HEALTH PLANNING AND PUBLIC HEALTH SERVICES

Grants to States for Comprehensive State Health Planning

SEC. 314. [246] (a)(1) AUTHORIZATION.—In order to assist the States in comprehensive and continuing planning for their current and future health needs, the Secretary is authorized during the period beginning July 1, 1966, and ending June 30, 1973, to make grants to States which have submitted, and had approved by the Secretary, State plans for comprehensive State health planning. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated \$2,500,000 for the fiscal year ending June 30, 1967, \$7,000,000 for the fiscal year ending June 30, 1968, \$10,000,000 for the fiscal year ending June 30, 1969, \$15,000,000 for the fiscal year ending June 30, 1970, \$15,000,000 for the fiscal year ending June 30, 1971, \$17,000,000 for the fiscal year ending June 30, 1972, \$20,000,000 for the fiscal year ending June 30, 1973, and \$10,000,000 for the fiscal year ending June 30, 1974.

(2) STATE PLANS FOR COMPREHENSIVE STATE HEALTH PLANNING.—In order to be approved for purposes of this subsection, a State plan for comprehensive State health planning must—

(A) designate, or provide for the establishment of, a single State agency, which may be an interdepartmental agency, as the sole agency for administering or supervising the administration of the State's health planning functions under the plan;

(B) provide for the establishment of a State health planning council, which shall include representatives of Federal, State, and local agencies (including as an ex officio member, if there is located in such State one or more hospitals or other health care facilities of the Department of Veterans Affairs, the individual whom the Secretary of Veterans Affairs shall have designated to serve on such council as the representative of the hospitals or other health care facilities of such Department which are located in such State) and nongovernmental organi-

zations and groups concerned with health (including representation of the regional medical program or programs included in whole or in part within the State) and of consumers of health services, to advise such State agency in carrying out its functions under the plan, and a majority of the membership of such council shall consist of representatives of consumers of health services;

(C) set forth policies and procedures for the expenditure of funds under the plan, which, in the judgment of the Secretary, are designed to provide for comprehensive State planning for health services (both public and private and including home health care), including the facilities and persons required for the provision of such services, to meet the health needs of the people of the State and including environmental considerations as they relate to public health;

(D) provide for encouraging cooperative efforts among governmental or nongovernmental agencies, organizations and groups concerned with health services, facilities, or manpower, and for cooperative efforts between such agencies, organizations, and groups and similar agencies, organizations, and groups in the fields of education, welfare, and rehabilitation;

(E) contain or be supported by assurances satisfactory to the Secretary that the funds paid under this subsection will be used to supplement and, to the extent practicable, to increase the level of funds that would otherwise be made available by the State for the purpose of comprehensive health planning and not to supplant such non-Federal funds;

(F)¹ provide such methods of administration (including methods relating to the establishment and maintenance of personnel standards on a merit basis, except that the Secretary shall exercise no authority with respect to the selection, tenure of office, and compensation of any individual employed in accordance with such methods) as are found by the Secretary to be necessary for the proper and efficient operation of the plan;

(G) provide that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time reasonably require, and will keep such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of such reports;

(H) provide that the State agency will from time to time, but not less often than annually, review its State plan approved under this subsection and submit to the Secretary appropriate modifications thereof;

(I) effective July 1, 1968, (i) provide for assisting each health care facility in the State to develop a program for capital expenditures for replacement, modernization, and expansion which is consistent with an overall State plan developed

¹Section 208(a)(3) of Public Law 91-648 (42 U.S.C. 4728) transferred to the United States Civil Service Commission all functions, powers, and duties of the Secretary under any law applicable to a grant program which requires the establishment and maintenance of personnel standards on a merit basis with respect to the program. Reorganization Plan No. 2 of 1978 (42 U.S.C. 1101 note) transferred to the Office of Personnel Management all functions of the United States Civil Service Commission.

in accordance with criteria established by the Secretary after consultation with the State which will meet the needs of the State for health care facilities, equipment, and services without duplication and otherwise in the most efficient and economical manner, and (ii) provide that the State agency furnishing such assistance will periodically review the program (developed pursuant to clause (i)) of each health care facility in the State and recommended appropriate modification thereof;

(J) provide for such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for funds paid to the State under this subsection; and

(K) contain such additional information and assurances as the Secretary may find necessary to carry out the purposes of this subsection.

(3)(A) STATE ALLOTMENTS.—From the sums appropriated for such purpose for each fiscal year, the several States shall be entitled to allotments determined, in accordance with regulations, on the basis of the population and the per capita income of the respective States; except that no such allotment to any State for any fiscal year shall be less than 1 per centum of the sum appropriated for such fiscal year pursuant to paragraph (1). Any such allotment to a State for a fiscal year shall remain available for obligation by the State, in accordance with the provisions of this subsection and the State's plan approved thereunder, until the close of the succeeding fiscal year.

(B) The amount of any allotment to a State under subparagraph (A) for any fiscal year which the Secretary determines will not be required by the State, during the period for which it is available, for the purposes for which allotted shall be available for reallocation by the Secretary from time to time, on such date or dates as he may fix, to other States with respect to which such a determination has not been made, in proportion to the original allotments to such States under subparagraph (A) for such fiscal year, but with such proportionate amount for any of such other States being reduced to the extent it exceeds the sum the Secretary estimates such State needs and will be able to use during such period; and the total of such reductions shall be similarly reallocated among the States whose proportionate amounts were not so reduced. Any amount so reallocated to a State from funds appropriated pursuant to this subsection for a fiscal year shall be deemed part of its allotment under subparagraph (A) for such fiscal year.

(4) PAYMENTS TO STATES.—From each State's allotment for a fiscal year under this subsection, the State shall from time to time be paid the Federal share of the expenditures incurred during that year or the succeeding year pursuant to its State plan approved under this subsection. Such payments shall be made on the basis of estimates by the Secretary of the sums the State will need in order to perform the planning under its approved State plan under this subsection, but with such adjustments as may be necessary to take account of previously made underpayments or overpayments. The "Federal share" for any State for purposes of this subsection shall be all, or such part as the Secretary may determine, of the cost of such planning, except that in the case of the allotments for

the fiscal year ending June 30, 1970, it shall not exceed 75 per centum, of such cost.

Project Grants for Areawide Health Planning

(b)(1)(A) The Secretary is authorized, during the period beginning July 1, 1966, and ending June 30, 1974, to make, with the approval of the State agency administering or supervising the administration of the State plan approved under subsection (a), project grants to any other public or nonprofit private agency or organization (but with appropriate representation of the interests of local government where the recipient of the grant is not a local government or combination thereof or an agency of such government or combination) to cover not to exceed 75 per centum of the costs of projects for developing (and from time to time revising) comprehensive regional, metropolitan area, or other local area plans for coordination of existing and planned health services, including the facilities and persons required for provision of such services; and including the provision of such services through home health care; except that in the case of project grants made in any State prior to July 1, 1968, approval of such State agency shall be required only if such State has such a State plan in effect at the time of such grants. No grant may be made under this subsection after June 30, 1970, to any agency or organization to develop or revise health plans for an area unless the Secretary determines that such agency or organization provides means for appropriate representation of the interests of the hospitals, other health care facilities, and practicing physicians serving such area, and the general public. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated \$5,000,000 for the fiscal year ending June 30, 1967, \$7,500,000 for the fiscal year ending June 30, 1968, \$10,000,000 for the fiscal year ending June 30, 1969, \$15,000,000 for the fiscal year ending June 30, 1970, \$20,000,000 for the fiscal year ending June 30, 1971, \$30,000,000 for the fiscal year ending June 30, 1972, \$40,000,000 for the fiscal year ending June 30, 1973, and \$25,100,000 for the fiscal year ending June 30, 1974.

(B) Project grants may be made by the Secretary under subparagraph (A) to the State agency administering or supervising the administration of the State plan approved under subsection (a) with respect to a particular region or area, but only if (i) no application for such a grant with respect to such region or area has been filed by any other agency or organization qualified to receive such a grant, and (ii) such State agency certifies, and the Secretary finds, that ample opportunity has been afforded to qualified agencies and organizations to file application for such a grant with respect to such region or area and that it is improbable that, in the foreseeable future, any agency or organization which is qualified for such a grant will file application therefor.

(2)(A) In order to be approved under this subsection, an application for a grant under this subsection must contain or be supported by reasonable assurances that there has been or will be established, in or for the area with respect to which such grant is sought, an areawide health planning council. The membership of

such council shall include representatives of public, voluntary, and non-profit private agencies, institutions, and organizations concerned with health (including representatives of the interests of local government of the regional medical program for such area, and of consumers of health services). A majority of the members of such council shall consist of representatives of consumers of health services.

(B) In addition, an application for a grant under this subsection must contain or be supported by reasonable assurances that the areawide health planning agency has made provision for assisting health care facilities in its area to develop a program for capital expenditures for replacement, modernization, and expansion, which is consistent with an overall State plan which will meet the needs of the State and the area for health care facilities, equipment, and services without duplication and otherwise in the most efficient and economical manner.

Project Grants for Training, Studies, and Demonstrations

(c) The Secretary is also authorized, during the period beginning July 1, 1966, and ending June 30, 1974, to make grants to any public or nonprofit private agency, institution, or other organization to cover all or any part of the cost of projects for training, studies, or demonstrations looking toward the development of improved or more effective comprehensive health planning throughout the Nation. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated \$1,500,000 for the fiscal year ending June 30, 1967, \$2,500,000 for the fiscal year ending June 30, 1968, \$5,000,000 for the fiscal year ending June 30, 1969, \$7,500,000 for the fiscal year ending June 30, 1970, \$8,000,000 for the fiscal year ending June 30, 1971, \$10,000,000 for the fiscal year ending June 30, 1972, \$12,000,000 for the fiscal year ending June 30, 1973, and \$4,700,000 for the fiscal year ending June 30, 1974.

FAMILY SUPPORT GROUPS FOR ALZHEIMER'S DISEASE PATIENTS

SEC. 316.¹ [247a] (a) Subject to available appropriations, the Secretary, acting through the National Institute of Mental Health, the National Institutes of Health, and the Administration on Aging, shall promote the establishment of family support groups to provide, without charge, educational, emotional, and practical support to assist individuals with Alzheimer's disease or a related memory disorder and members of the families of such individuals. In promoting the establishment of such groups, the Secretary shall give priority to—

(1) university medical centers and other appropriate health care facilities which receive Federal funds from the Secretary and which conduct research on Alzheimer's disease or provide services to individuals with such disease; and

(2) community-based programs which receive funds from the Secretary, acting through the Administration on Aging.

¹Former section 315 (relating to grants for treatment drugs for acquired immune deficiency syndrome) was repealed on March 31, 1989, by subsection (d) of such section.

(b) The Secretary shall promote the establishment of a national network to coordinate the family support groups described in subsection (a).

PROJECT GRANTS FOR PREVENTIVE HEALTH SERVICES

SEC. 317. [247b] (a) The Secretary may make grants to States, and in consultation with State health authorities, to political subdivisions of States and to other public entities to assist them in meeting the costs of establishing and maintaining preventive health service programs.

(b) No grant may be made under subsection (a) unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and be submitted in such manner as the Secretary shall by regulation prescribe and shall provide—

(1) a complete description of the type and extent of the program for which the applicant is seeking a grant under subsection (a);

(2) with respect to each such program (A) the amount of Federal, State, and other funds obligated by the applicant in its latest annual accounting period for the provision of such program, (B) a description of the services provided by the applicant in such program in such period, (C) the amount of Federal funds needed by the applicant to continue providing such services in such program, and (D) if the applicant proposes changes in the provision of the services in such program, the priorities of such proposed changes, reasons for such changes, and the amount of Federal funds needed by the applicant to make such changes;

(3) assurances satisfactory to the Secretary that the program which will be provided with funds under a grant under subsection (a) will be provided in a manner consistent with the State health plan in effect under section 1524(c) and in those cases where the applicant is a State, that such program will be provided, where appropriate, in a manner consistent with any plans in effect under an application approved under section 315;

(4) assurances satisfactory to the Secretary that the applicant will provide for such fiscal control and fund accounting procedures as the Secretary by regulation prescribes to assure the proper disbursement of and accounting for funds received under grants under subsection (a);

(5) assurances satisfactory to the Secretary that the applicant will provide for periodic evaluation of its program or programs;

(6) assurances satisfactory to the Secretary that the applicant will make such reports (in such form and containing such information as the Secretary may by regulation prescribe) as the Secretary may reasonably require and keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness of, and to verify, such reports;

(7) assurances satisfactory to the Secretary that the applicant will comply with any other conditions imposed by this section with respect to grants; and

(8) such other information as the Secretary may by regulation prescribe.

(c)(1) The Secretary shall not approve an application submitted under subsection (b) for a grant for a program for which a grant was previously made under subsection (a) unless the Secretary determines—

(A) the program for which the application was submitted is operating effectively to achieve its stated purpose,

(B) the applicant complied with the assurances provided the Secretary when applying for such previous grant, and

(C) the applicant will comply with the assurances provided with the application.

(2) The Secretary shall review annually the activities undertaken by each recipient of a grant under subsection (a) to determine if the program assisted by such grant is operating effectively to achieve its stated purposes and if the recipient is in compliance with the assurances provided the Secretary when applying for such grant.

(d) The amount of a grant under subsection (a) shall be determined by the Secretary. Payments under such grants may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

(e) The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(1) the fair market value of any supplies (including vaccines and other preventive agents) or equipment furnished the grant recipient, and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee.

When the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(f)(1) Each recipient of a grant under subsection (a) shall keep such records as the Secretary shall by regulation prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the undertaking in connection with which such grant was made, and the amount of that portion of the cost of the undertaking supplied by

other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of grants under subsection (a) that are pertinent to such grants.

(g)(1) Nothing in this section shall limit or otherwise restrict the use of funds which are granted to a State or to an agency or a political subdivision of a State under provisions of Federal law (other than this section) and which are available for the conduct of preventive health service programs from being used on connection with programs assisted through grants under subsection (a).

(2) Nothing in this section shall be construed to require any State or any agency or political subdivision of a State to have a preventive health service program which would require any person, who objects to any treatment provided under such a program, to be treated or to have any child or ward treated under such program.

(h) The Secretary shall include, as part of the report required by section 1705, a report on the extent of the problems presented by the diseases and conditions referred to in subsection (j) on the amount of funds obligated under grants under subsection (a) in the preceding fiscal year for each of the programs listed in subsection (j); and on the effectiveness of the activities assisted under grants under subsection (a) in controlling such diseases and conditions.

(i) The Secretary may provide technical assistance to States, State health authorities, and other public entities in connection with the operation of their preventive health service programs.

(j)(1) Except for grants for immunization programs the authorization of appropriations for which are established in paragraph (2), for grants under subsections (a) and (k)(1) for preventive health service programs to immunize without charge individuals against vaccine-preventable diseases, there are authorized to be appropriated \$205,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995. Not more than 10 percent of the total amount appropriated under the preceding sentence for any fiscal year shall be available for grants under subsection (k)(1) for such fiscal year.

(2) For grants under subsection (a) for preventive health service programs for the provision without charge of immunizations with vaccines approved for use, and recommended for routine use, after October 1, 1990, there are authorized to be appropriated such sums as may be necessary.

(k)(1) The Secretary may make grants to States, political subdivisions of States, and other public and nonprofit private entities for—

(A) research into the prevention and control of diseases that may be prevented through vaccination;

(B) demonstration projects for the prevention and control of such diseases;

(C) public information and education programs for the prevention and control of such diseases; and

(D) education, training, and clinical skills improvement activities in the prevention and control of such diseases for health professionals (including allied health personnel).

(2) The Secretary may make grants to States, political subdivisions of States, and other public and nonprofit private entities for—

(A) research into the prevention and control of diseases and conditions;

(B) demonstration projects for the prevention and control of such diseases and conditions;

(C) public information and education programs for the prevention and control of such diseases and conditions; and

(D) education, training, and clinical skills improvement activities in the prevention and control of such diseases and conditions for health professionals (including allied health personnel).

(3) No grant may be made under this subsection unless an application therefor is submitted to the Secretary in such form, at such time, and containing such information as the Secretary may by regulation prescribe.

(4) Subsections (d), (e), and (f) shall apply to grants under this subsection in the same manner as such subsections apply to grants under subsection (a).

SCREENINGS, REFERRALS, AND EDUCATION REGARDING LEAD POISONING

SEC. 317A. [247b-1] (a) AUTHORITY FOR GRANTS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States and political subdivisions of States for the initiation and expansion of community programs designed—

(A) to provide, for infants and children—

(i) screening for elevated blood lead levels;

(ii) referral for treatment of such levels; and

(iii) referral for environmental intervention associated with such levels; and

(B) to provide education about childhood lead poisoning.

(2) AUTHORITY REGARDING CERTAIN ENTITIES.—With respect to a geographic area with a need for activities authorized in paragraph (1), in any case in which neither the State nor the political subdivision in which such area is located has applied for a grant under paragraph (1), the Secretary may make a grant under such paragraph to any grantee under section 329, 330, 340, or 340A for carrying out such activities in the area.

(3) PROVISION OF ALL SERVICES AND ACTIVITIES THROUGH EACH GRANTEE.—In making grants under paragraph (1), the Secretary shall ensure that each of the activities described in such paragraph is provided through each grantee under such paragraph. The Secretary may authorize such a grantee to provide the services and activities directly, or through arrangements with other providers.

(b) STATUS AS MEDICAID PROVIDER.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may not make a grant under subsection (a) unless, in the case of any service described in such subsection that is made available pursuant to the State plan approved under title XIX of the Social Security Act for the State involved—

(A) the applicant for the grant will provide the service directly, and the applicant has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(B) the applicant will enter into an agreement with a provider under which the provider will provide the service, and the provider has entered into such a participation agreement and is qualified to receive such payments.

(2) WAIVER REGARDING CERTAIN SECONDARY AGREEMENTS.—

(A) In the case of a provider making an agreement pursuant to paragraph (1)(B) regarding the provision of services, the requirement established in such paragraph regarding a participation agreement shall be waived by the Secretary if the provider does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits plan.

(B) A determination by the Secretary of whether a provider referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the provider accepts voluntary donations regarding the provision of services to the public.

(c) PRIORITY IN MAKING GRANTS.—In making grants under subsection (a), the Secretary shall give priority to applications for programs that will serve areas with a high incidence of elevated blood lead levels in infants and children.

(d) GRANT APPLICATION.—No grant may be made under subsection (a), unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall prescribe and shall include each of the following:

(1) A complete description of the program which is to be provided by or through the applicant.

(2) Assurances satisfactory to the Secretary that the program to be provided under the grant applied for will include educational programs designed to—

(A) communicate to parents, educators, and local health officials the significance and prevalence of lead poisoning in infants and children (including the sources of lead exposure, the importance of screening young children for lead, and the preventive steps that parents can take in reducing the risk of lead poisoning) which the program is designed to detect and prevent; and

(B) communicate to health professionals and para-professionals updated knowledge concerning lead poisoning and research (including the health consequences, if any, of low-level lead burden; the prevalence of lead poisoning

among all socioeconomic groupings; the benefits of expanded lead screening; and the therapeutic and other interventions available to prevent and combat lead poisoning in affected children and families).

(3) Assurances satisfactory to the Secretary that the applicant will report on a quarterly basis the number of infants and children screened for elevated blood lead levels, the number of infants and children who were found to have elevated blood lead levels, the number and type of medical referrals made for such infants and children, the outcome of such referrals, and other information to measure program effectiveness.

(4) Assurances satisfactory to the Secretary that the applicant will make such reports respecting the program involved as the Secretary may require.

(5) Assurances satisfactory to the Secretary that the applicant will coordinate the activities carried out pursuant to subsection (a) with related activities and services carried out in the State by grantees under title V or XIX of the Social Security Act.

(6) Assurances satisfactory to the Secretary that Federal funds made available under such a grant for any period will be so used as to supplement and, to the extent practical, increase the level of State, local, and other non-Federal funds that would, in the absence of such Federal funds, be made available for the program for which the grant is to be made and will in no event supplant such State, local, and other non-Federal funds.

(7) Such other information as the Secretary may prescribe.

(e) RELATIONSHIP TO SERVICES AND ACTIVITIES UNDER OTHER PROGRAMS.—

(1) IN GENERAL.—A recipient of a grant under subsection (a) may not make payments from the grant for any service or activity to the extent that payment has been made, or can reasonably be expected to be made, with respect to such service or activity—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(B) by an entity that provides health services on a prepaid basis.

(2) APPLICABILITY TO CERTAIN SECONDARY AGREEMENTS FOR PROVISION OF SERVICES.—Paragraph (1) shall not apply in the case of a provider through which a grantee under subsection (a) provides services under such subsection if the Secretary has provided a waiver under subsection (b)(2) regarding the provider.

(f) METHOD AND AMOUNT OF PAYMENT.—The Secretary shall determine the amount of a grant made under subsection (a). Payments under such grants may be made in advance on the basis of estimates or by way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants. Not more than 10 percent of any grant may be obligated for administrative costs.

(g) **SUPPLIES, EQUIPMENT, AND EMPLOYEE DETAIL.**—The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(1) the fair market value of any supplies or equipment furnished the grant recipient; and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee; when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(h) **RECORDS.**—Each recipient of a grant under subsection (a) shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the undertaking in connection with which such grant was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(i) **AUDIT AND EXAMINATION OF RECORDS.**—The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant under subsection (a), that are pertinent to such grant.

(j) **ANNUAL REPORT.**—

(1) **IN GENERAL.**—Not later than May 1 of each year, the Secretary shall submit to the Congress a report on the effectiveness during the preceding fiscal year of programs carried out with grants under subsection (a) and of any programs that are carried out by the Secretary pursuant to subsection (1)(2).

(2) **CERTAIN REQUIREMENTS.**—Each report under paragraph (1) shall include, in addition to any other information that the Secretary may require, the following information:

(A) The number of infants and children screened.

(B) Demographic information on the population of infants and children screened, including the age and racial or ethnic status of such population.

(C) The number of screening sites.

(D) A description of the severity of the extent of the blood lead levels of the infants and children screened, expressed in categories of severity.

(E) The sources of payment for the screenings.

(F) A comparison of the data provided pursuant to subparagraphs (A) through (E) with the equivalent data, if

any, provided in the report under paragraph (1) preceding the report involved.

(k) INDIAN TRIBES.—For purposes of this section, the term “political subdivision” includes Indian tribes.

(l) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$40,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 1998.

(2) ALLOCATION FOR OTHER PROGRAMS.—Of the amounts appropriated under paragraph (1) for any fiscal year, the Secretary may reserve not more than 20 percent for carrying out programs regarding the activities described in subsection (a) in addition to the program of grants established in such subsection.

EDUCATION, TECHNOLOGY ASSESSMENT, AND EPIDEMIOLOGY
REGARDING LEAD POISONING

SEC. 317B. [247b–3] (a) PREVENTION.—

(1) PUBLIC EDUCATION.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out a program to educate health professionals and paraprofessionals and the general public on the prevention of lead poisoning in infants and children. In carrying out the program, the Secretary shall make available information concerning the health effects of low-level lead toxicity, the causes of lead poisoning, and the primary and secondary preventive measures that may be taken to prevent such poisoning.

(2) INTERAGENCY TASK FORCE.—

(A) Not later than 6 months after the date of the enactment of the Preventive Health Amendments of 1992¹, the Secretary shall establish a council to be known as the Interagency Task Force on the Prevention of Lead Poisoning (in this paragraph referred to as the “Task Force”). The Task Force shall coordinate the efforts of Federal agencies to prevent lead poisoning.

(B) The Task Force shall be composed of—

(i) the Secretary, who shall serve as the chair of the Task Force;

(ii) the Secretary of Housing and Urban Development;

(iii) the Administrator of the Environmental Protection Agency; and

(iv) senior staff of each of the officials specified in clauses (i) through (iii), as selected by the officials respectively.

(C) The Task Force shall—

(i) review, evaluate, and coordinate current strategies and plans formulated by the officials serving as members of the Task Force, including—

(I) the plan of the Secretary of Health and Human Services entitled “Strategic Plan for the

¹ Enacted October 27, 1992.

Elimination of Lead Poisoning", dated February 21, 1991;

(II) the plan of the Secretary of Housing and Urban Development entitled "Comprehensive and Workable Plan for the Abatement of Lead-Based Paint in Privately Owned Housing", dated December 7, 1990; and

(III) the strategy of the Administrator of the Environmental Protection Agency entitled "Strategy for Reducing Lead Exposures", dated February 21, 1991;

(ii) develop a unified implementation plan for programs that receive Federal financial assistance for activities related to the prevention of lead poisoning;

(iii) establish a mechanism for sharing and disseminating information among the agencies represented on the Task Force;

(iv) identify the most promising areas of research and education concerning lead poisoning;

(v) identify the practical and technological constraints to expanding lead poisoning prevention;

(vi) annually carry out a comprehensive review of Federal programs providing assistance to prevent lead poisoning, and not later than May 1 of each year, submit to the Committee on Labor and Human Resources of the Senate and the Committee on the Environment and Public Works of the Senate, and to the Committee on Energy and Commerce of the House of Representatives, a report that summarizes the findings made as a result of such review and that contains the recommendations of the Task Force on the programs and policies with respect to which the Task Force is established, including related budgetary recommendations; and

(vii) annually review and coordinate departmental and agency budgetary requests with respect to all lead poisoning prevention activities of the Federal Government.

(b) TECHNOLOGY ASSESSMENT AND EPIDEMIOLOGY.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, directly or through grants or contracts—

(1) provide for the development of improved, more cost-effective testing measures for detecting lead toxicity in children;

(2) provide for the development of improved methods of assessing the prevalence of lead poisoning, including such methods as may be necessary to conduct individual assessments for each State;

(3) provide for the collection of data on the incidence and prevalence of lead poisoning of infants and children, on the demographic characteristics of infants and children with such poisoning (including racial and ethnic status), and on the source of payment for treatment for such poisoning (including the extent to which insurance has paid for such treatment); and

(4) provide for any applied research necessary to improve the effectiveness of programs for the prevention of lead poisoning in infants and children.

COLLECTION OF DATA ON BIRTH DEFECTS

SEC. 317C. [247b-4] (a) STATE PROGRAMS.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall encourage States to establish or improve programs for the collection and analysis of epidemiological data on birth defects.

(2) PROVISION OF ASSISTANCE.—The Secretary may, directly or through grants, cooperative agreements, or contracts, provide assistance to States regarding the purpose specified in subsection (a).¹

(b) NATIONAL CLEARINGHOUSE.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish and maintain a National Information Clearinghouse on Birth Defects to collect and disseminate to health professionals and the general public information on birth defects, including the prevention of such defects.

(c) REPORT.—Not later than July 1, 1993, and biennially thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report describing activities carried out under this section and containing any recommendations of the Secretary regarding this section.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$5,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 and 1995.

PREVENTIVE HEALTH MEASURES WITH RESPECT TO PROSTATE CANCER

SEC. 317D. [247b-5] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States and local health departments for the purpose of enabling such States and departments to carry out programs—

(1) to screen men for prostate cancer as a preventive health measure;

(2) to provide appropriate referrals for medical treatment of men screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services;

(3) to develop and disseminate public information and education programs for the detection and control of prostate cancer;

(4) to improve the education, training, and skills of health professionals (including appropriate allied health professionals) in the detection and control of prostate cancer;

(5) to establish mechanisms through which the States and such departments can monitor the quality of screening proce-

¹So in law. See section 306 of Public Law 102-531 (106 Stat. 3494). Probably should be "paragraph (1)".

dures for prostate cancer, including the interpretation of such procedures; and

(6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate surveillance or program monitoring activities.

(b) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under paragraph (2)) toward such costs in an amount equal to not less than \$1 for each \$3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) In making a determination of the amount of non-Federal contributions for purposes of paragraph (1), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the applicant involved toward the purpose described in subsection (a) for the 2-year period preceding the fiscal year for which the applicant involved is applying to receive a grant under such subsection.

(C) In making a determination of the amount of non-Federal contributions for purposes of paragraph (1), the Secretary shall, subject to subparagraphs (A) and (B) of this paragraph, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act by the applicant involved toward the purpose described in paragraphs (1) and (2) of subsection (a).

(c) EDUCATION ON SIGNIFICANCE OF EARLY DETECTION.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that, in carrying out subsection (a)(3), the applicant will carry out education programs to communicate to men, and to local health officials, the significance of the early detection of prostate cancer.

(d) REQUIREMENT OF PROVISION OF ALL SERVICES BY DATE CERTAIN.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees—

(1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of such subsection;

(2) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in such subsection is provided; and

(3) to ensure that not more than 40 percent of the grant is expended to provide the services or activities described in paragraphs (3) through (6) of such section.

(e) ADDITIONAL REQUIRED AGREEMENTS.—

(1) PRIORITY FOR LOW-INCOME MEN.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that low-income men, and men at risk of prostate cancer, will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of such subsection.

(2) LIMITATION ON IMPOSITION OF FEES FOR SERVICES.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(A) will be made according to a schedule of charges that is made available to the public;

(B) will be adjusted to reflect the income of the man involved; and

(C) will not be imposed on any man with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(3) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(B) by an entity that provides health services on a prepaid basis.

(4) COORDINATION WITH OTHER PROSTATE CANCER PROGRAMS.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that the services and activities funded through the grant will be coordinated with other Federal, State, and local prostate cancer programs.

(5) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(6) RESTRICTIONS ON USE OF GRANT.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.

(7) RECORDS AND AUDITS.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that—

(A) the applicant will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the applicant under such section; and

(B) upon request, the applicant will provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller of the United States for purposes of auditing the expenditures by the applicant of the grant.

(f) REPORTS TO SECRETARY.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

(g) DESCRIPTION OF INTENDED USES OF GRANT.—The Secretary may not make a grant under subsection (a) unless—

(1) the applicant involved submits to the Secretary a description of the purposes for which the applicant intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the applicant with a need for the services or activities described in subsection (a);

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public or nonprivate entities; and

(4) the description provides assurances that the grant funds will be used in the most cost-effective manner.

(h) REQUIREMENT OF SUBMISSION OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in subsection (g), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(i) METHOD AND AMOUNT OF PAYMENT.—The Secretary shall determine the amount of a grant made under subsection (a). Payments under such grants may be made in advance on the basis of estimates or by way of reimbursement, with necessary adjustments on account of the underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

(j) TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) TECHNICAL ASSISTANCE.—The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to subsection (a). The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.

(2) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(A) Upon the request of an applicant receiving a grant under subsection (a), the Secretary may, subject to subparagraph (B), provide supplies, equipment, and services for the purpose of aiding the applicant in carrying out such section and, for such purpose, may detail to the applicant any officer or employee of the Department of Health and Human Services.

(B) With respect to a request described in subparagraph (A), the Secretary shall reduce the amount of payments under the grant under subsection (a) to the applicant involved by an amount equal to the costs of detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(k) DEFINITION.—For purposes of this section, the term “units of local government” includes Indian tribes.

(l) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated \$20,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 1998.

(2) ALLOCATION FOR TECHNICAL ASSISTANCE.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out subsection (j)(1).

PREVENTIVE HEALTH SERVICES REGARDING TUBERCULOSIS

SEC. 317E. [247b–6] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States, political subdivisions, and other public entities for preventive health service programs for the prevention, control, and elimination of tuberculosis.

(b) RESEARCH, DEMONSTRATION PROJECTS, EDUCATION, AND TRAINING.—With respect to the prevention, control, and elimination of tuberculosis, the Secretary may, directly or through grants to public or nonprofit private entities, carry out the following:

(1) Research, with priority given to research concerning strains of tuberculosis resistant to drugs and research concerning cases of tuberculosis that affect certain populations.

(2) Demonstration projects.

(3) Public information and education programs.

(4) Education, training, and clinical skills improvement activities for health professionals, including allied health personnel and emergency response employees.

(5) Support of centers to carry out activities under paragraphs (1) through (4).

(6) Collaboration with international organizations and foreign countries in carrying out such activities.

(c) COOPERATION WITH PROVIDERS OF PRIMARY HEALTH SERVICES.—The Secretary may make a grant under subsection (a) or (b) only if the applicant for the grant agrees that, in carrying out activities under the grant, the applicant will cooperate with public

and nonprofit private providers of primary health services or substance abuse services, including entities receiving assistance under section 329, 330, 340, or 340A or under title V or XIX.

(d) APPLICATION FOR GRANT.—

(1) IN GENERAL.—The Secretary may make a grant under subsection (a) or (b) only if an application for the grant is submitted to the Secretary and the application, subject to paragraph (2), is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the subsection involved.

(2) PLAN FOR PREVENTION, CONTROL, AND ELIMINATION.—The Secretary may make a grant under subsection (a) only if the application under paragraph (1) contains a plan regarding the prevention, control, and elimination of tuberculosis in the geographic area with respect to which the grant is sought.

(e) SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) IN GENERAL.—Upon the request of a grantee under subsection (a) or (b), the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the grantee in carrying out the subsection involved and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) CORRESPONDING REDUCTION IN PAYMENTS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(f) ADVISORY COUNCIL.—

(1) IN GENERAL.—The Secretary shall establish an advisory council to be known as the Advisory Council for the Elimination of Tuberculosis (in this subsection referred to as the "Council").

(2) GENERAL DUTIES.—The Council shall provide advice and recommendations regarding the elimination of tuberculosis to the Secretary, the Assistant Secretary for Health, and the Director of the Centers for Disease Control and Prevention.

(3) CERTAIN ACTIVITIES.—With respect to the elimination of tuberculosis, the Council shall—

(A) in making recommendations under paragraph (2), make recommendations regarding policies, strategies, objectives, and priorities;

(B) address the development and application of new technologies; and

(C) review the extent to which progress has been made toward eliminating tuberculosis.

(4) COMPOSITION.—The Secretary shall determine the size and composition of the Council, and the frequency and scope of official meetings of the Council.

(5) STAFF, INFORMATION, AND OTHER ASSISTANCE.—The Secretary shall provide to the Council such staff, information,

and other assistance as may be necessary to carry out the duties of the Council.

(g) FUNDING.—

(1) IN GENERAL; ALLOCATION FOR EMERGENCY GRANTS.—

(A) For the purpose of making grants under subsection (a), there are authorized to be appropriated \$200,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.

(B) Of the amounts appropriated under subparagraph (A) for a fiscal year, the Secretary may reserve not more than \$50,000,000 for emergency grants under subsection (a) for any geographic area in which there is, relative to other areas, a substantial number of cases of tuberculosis or a substantial rate of increase in such cases.

(2) RESEARCH, DEMONSTRATION PROJECTS, EDUCATION, AND TRAINING.—For the purpose of making grants under subsection (b), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1998.

LOAN REPAYMENT PROGRAM

SEC. 317F. [247b-7] (a) IN GENERAL.—

(1) AUTHORITY.—Subject to paragraph (2), the Secretary may carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct prevention activities, as employees of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than \$20,000 of the principal and interest of the educational loans of such health professionals.

(2) LIMITATION.—The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee of the Centers for Disease Control and Prevention or the Agency for Toxic Substances and Disease Registry for purposes of paragraph (1) for a period of not less than 3 years.

(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III of this Act, the provisions of such subpart shall, except as inconsistent with subsection (a), apply to the program established in this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$500,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.

PROJECTS AND PROGRAMS FOR THE PREVENTION AND CONTROL OF
SEXUALLY TRANSMITTED DISEASES ¹

SEC. 318. [247c] (a) The Secretary may provide technical assistance to appropriate public and non-profit private entities and to scientific institutions for their research in, and training and public health programs for the prevention and control of sexually transmitted diseases.

(b) The Secretary may make grants to States, political subdivisions of States, and any other public and nonprofit private entity for—

(1) research into the prevention and control of sexually transmitted diseases;

(2) demonstration projects for the prevention and control of sexually transmitted diseases;

(3) public information and education programs for the prevention and control of such diseases; and

(4) education, training, and clinical skills improvement activities in the prevention and control of such diseases for health professionals (including allied health personnel).

(c) The Secretary is also authorized to make project grants to States and, in consultation with the State health authority, to political subdivisions of States, for—

(1) sexually transmitted diseases surveillance activities, including the reporting, screening, and followup of diagnostic tests for, and diagnosed cases of, sexually transmitted diseases;

(2) casefinding and case followup activities respecting sexually transmitted diseases, including contact tracing of infectious cases of sexually transmitted diseases and routine testing, including laboratory tests and followup systems;

(3) interstate epidemiologic referral and followup activities respecting sexually transmitted diseases; and

(4) such special studies or demonstrations to evaluate or test sexually transmitted diseases prevention and control strategies and activities as may be prescribed by the Secretary.

(d) The Secretary may make grants to States and political subdivisions of States for the development, implementation, and evaluation of innovative, interdisciplinary approaches to the prevention and control of sexually transmitted diseases.

(e)(1) For the purpose of making grants under subsections (b) through (d), there are authorized to be appropriated \$85,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.

(2) Each recipient of a grant under this section shall keep such records as the Secretary shall prescribe including records which fully disclose the amount and disposition by such recipient of the

¹Title II of Public Law 103-333, an appropriations Act, provides (under the heading relating to the Centers for Disease Control and Prevention; see 108 Stat. 2550) in part as follows: "That funds appropriated under this heading for fiscal year 1995 and subsequent fiscal years shall be available for payment of the costs of medical care, related expenses, and burial expenses hereafter incurred by or on behalf of any person who had participated in the study of untreated syphilis initiated in Tuskegee, Alabama, in 1932, in such amounts and subject to such terms and conditions as prescribed by the Secretary of Health and Human Services and for payment, in such amounts and subject to such terms and conditions, of such costs and expenses hereafter incurred by or on behalf of such person's wife or offspring determined by the Secretary to have suffered injury or disease from syphilis contracted from such person".

proceeds of such grant, the total cost of the project or undertaking in connection with which such grant was given or used and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(3) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients of grants under this section that are pertinent to such grants.

(4) The Secretary, at the request of a recipient of a grant under this section, may reduce such grant by the fair market value of any supplies or equipment furnished to such recipient and by the amount of pay, allowances, travel expenses, and any other costs in connection with the detail of an officer or employee of the United States to the recipient when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such recipient and for the purpose of carrying out the program with respect to which the grant under this section is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies, equipment, or personal services on which the reduction of such grant is based.

(5)¹ All information obtained in connection with the examination, care, or treatment of any individual under any program which is being carried out with a grant made under this section shall not, without such individual's consent, be disclosed except as may be necessary to provide service to him or as may be required by a law of a State or political subdivision of a State. Information derived from any such program may be disclosed—

(A) in summary, statistical, or other form, or

(B) for clinical or research purposes,

but only if the identity of the individuals diagnosed or provided care or treatment under such program is not disclosed.

(e)² Nothing in this section shall be construed to require any State or any political subdivision of a State to have a sexually transmitted diseases program which would require any person, who objects to any treatment provided under such a program, to be treated under such a program.

INFERTILITY AND SEXUALLY TRANSMITTED DISEASES

SEC. 318A. [247c-1] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States, political subdivisions of States, and other public or nonprofit private entities for the purpose of carrying out the activities described in subsection (c) regarding any treatable sexually transmitted disease that can cause infertility in women if treatment is not received for the disease.

¹Section 401(c) of Public Law 103-183 (107 Stat. 2236) provided for amendments to "subsection (d)(5)" in order to strike certain commas and insert semicolons. The amendments cannot be executed because the language to be amended does not appear in subsection (d). (The language appears in the first subsection (e), which was subsection (d) prior to being redesignated by section 401(a)(1) of such Public Law.)

²There are two subsections (e) in the law. See section 401(a)(1) of Public Law 103-183 (107 Stat. 2236).

(b) **AUTHORITY REGARDING INDIVIDUAL DISEASES.**—With respect to diseases described in subsection (a), the Secretary shall, in making a grant under such subsection, specify the particular disease or diseases with respect to which the grant is to be made. The Secretary may not make the grant unless the applicant involved agrees to carry out this section only with respect to the disease or diseases so specified.

(c) **AUTHORIZED ACTIVITIES.**—With respect to any sexually transmitted disease described in subsection (a), the activities referred to in such subsection are—

(1) screening women for the disease and for secondary conditions resulting from the disease, subject to compliance with criteria issued under subsection (f);

(2) providing treatment to women for the disease;

(3) providing counseling to women on the prevention and control of the disease (including, in the case of a woman with the disease, counseling on the benefits of locating and providing such counseling to any individual from whom the woman may have contracted the disease and any individual whom the woman may have exposed to the disease);

(4) providing follow-up services;

(5) referrals for necessary medical services for women screened pursuant to paragraph (1), including referrals for evaluation and treatment with respect to acquired immune deficiency syndrome and other sexually transmitted diseases;

(6) in the case of any woman receiving services pursuant to any of paragraphs (1) through (5), providing to the partner of the woman the services described in such paragraphs, as appropriate;

(7) providing outreach services to inform women of the availability of the services described in paragraphs (1) through (6);

(8) providing to the public information and education on the prevention and control of the disease, including disseminating such information; and

(9) providing training to health care providers in carrying out the screenings and counseling described in paragraphs (1) and (3).

(d) **REQUIREMENT OF AVAILABILITY OF ALL SERVICES THROUGH EACH GRANTEE.**—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that each activity authorized in subsection (c) will be available through the applicant. With respect to compliance with such agreement, the applicant may expend the grant to carry out any of the activities directly, and may expend the grant to enter into agreements with other public or nonprofit private entities under which the entities carry out the activities.

(e) **REQUIRED PROVIDERS REGARDING CERTAIN SERVICES.**—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that, in expending the grant to carry out activities authorized in subsection (c), the services described in paragraphs (1) through (7) of such subsection will be provided only through entities that are State or local health departments, grantees under section 329, 330, 340, 340A, or 1001, or are other public

or nonprofit private entities that provide health services to a significant number of low-income women.

(f) **QUALITY ASSURANCE REGARDING SCREENING FOR DISEASES.**—For purposes of this section, the Secretary shall establish criteria for ensuring the quality of screening procedures for diseases described in subsection (a).

(g) **CONFIDENTIALITY.**—The Secretary may make a grant under subsection (a) only if the applicant involved agrees, subject to applicable law, to maintain the confidentiality of information on individuals with respect to activities carried out under subsection (c).

(h) **LIMITATION ON IMPOSITION OF FEES FOR SERVICES.**—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the individual involved; and

(3) will not be imposed on any individual with an income of less than 150 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(i) **LIMITATIONS ON CERTAIN EXPENDITURES.**—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that not less than 80 percent of the grant will be expended for the purpose of carrying out paragraphs (1) through (7) of subsection (c).

(j) **REPORTS TO SECRETARY.**—

(1) **COLLECTION OF DATA.**—The Secretary may make a grant under subsection (a) only if the applicant involved agrees, with respect to any disease selected under subsection (b) for the applicant, to submit to the Secretary, for each fiscal year for which the applicant receives such a grant, a report providing—

(A) the incidence of the disease among the population of individuals served by the applicant;

(B) the number and demographic characteristics of individuals in such population;

(C) the types of interventions and treatments provided by the applicant, and the health conditions with respect to which referrals have been made pursuant to subsection (c)(5);

(D) an assessment of the extent to which the activities carried pursuant to subsection (a) have reduced the incidence of infertility in the geographic area involved; and

(E) such other information as the Secretary may require with respect to the project carried out with the grant.

(2) **UTILITY AND COMPARABILITY OF DATA.**—The Secretary shall carry out activities for the purpose of ensuring the utility and comparability of data collected pursuant to paragraph (1).

(k) **MAINTENANCE OF EFFORT.**—With respect to activities for which a grant under subsection (a) is authorized to be expended,

the Secretary may make such a grant only if the applicant involved agrees to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the average level of such expenditures maintained by the applicant for the 2-year period preceding the fiscal year for which the applicant is applying to receive such a grant.

(1) REQUIREMENT OF APPLICATION.—

(1) IN GENERAL.—The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary, the application contains the plan required in paragraph (2), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(2) SUBMISSION OF PLAN FOR PROGRAM OF GRANTEE.—

(A) IN GENERAL.—The Secretary may make a grant under subsection (a) only if the applicant involved submits to the Secretary a plan describing the manner in which the applicant will comply with the agreements required as a condition of receiving such a grant, including a specification of the entities through which activities authorized in subsection (c) will be provided.

(B) PARTICIPATION OF CERTAIN ENTITIES.—The Secretary may make a grant under subsection (a) only if the applicant provides assurances satisfactory to the Secretary that the plan submitted under subparagraph (A) has been prepared in consultation with an appropriate number and variety of—

(i) representatives of entities in the geographic area involved that provide services for the prevention and control of sexually transmitted diseases, including programs to provide to the public information and education regarding such diseases; and

(ii) representatives of entities in such area that provide family planning services.

(m) DURATION OF GRANT.—The period during which payments are made to an entity from a grant under subsection (a) may not exceed 3 years. The provision of such payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments in such year. The preceding sentence may not be construed to establish a limitation on the number of grants under such subsection that may be made to an entity.

(n) TECHNICAL ASSISTANCE, AND SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) TECHNICAL ASSISTANCE.—The Secretary may provide training and technical assistance to grantees under subsection (a) with respect to the planning, development, and operation of any program or service carried out under such subsection. The Secretary may provide such technical assistance directly or through grants or contracts.

(2) SUPPLIES, EQUIPMENT, AND EMPLOYEE DETAIL.—The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(A) the fair market value of any supplies or equipment furnished the grant recipient; and

(B) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee;

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(o) EVALUATIONS AND REPORTS BY SECRETARY.—

(1) EVALUATIONS.—The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to subsection (a) in order to determine the quality and effectiveness of the programs.

(2) REPORT TO CONGRESS.—Not later than 1 year after the date on which amounts are first appropriated pursuant to subsection (q), and biennially thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report—

(A) summarizing the information provided to the Secretary in reports made pursuant to subsection (j)(1), including information on the incidence of sexually transmitted diseases described in subsection (a); and

(B) summarizing evaluations carried out pursuant to paragraph (1) during the preceding fiscal year.

(p) COORDINATION OF FEDERAL PROGRAMS.—The Secretary shall coordinate the program carried out under this section with any similar programs administered by the Secretary (including coordination between the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health).

(q) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, other than subsections (o) and (r), there are authorized to be appropriated \$25,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 1998.

(r) SEPARATE GRANTS FOR RESEARCH ON DELIVERY OF SERVICES.—

(1) IN GENERAL.—The Secretary may make grants for the purpose of conducting research on the manner in which the delivery of services under subsection (a) may be improved. The Secretary may make such grants only to grantees under such subsection and to public and nonprofit private entities that are

carrying out programs substantially similar to programs carried out under such subsection.

(2) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out paragraph (1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1993 through 1998.

PUBLIC HEALTH EMERGENCIES

SEC. 319. [247d] (a) If the Secretary determines, after consultation with the Director of the National Institutes of Health, the Administrator of the Substance Abuse and Mental Health Services Administration, the Commissioner of the Food and Drug Administration, the Administrator of Health Resources and Services, or the Director of the Centers for Disease Control and Prevention, that—

(1) a disease or disorder presents a public health emergency, or

(2) a public health emergency otherwise exists and the Secretary has the authority to take action with respect to such emergency,

the Secretary, acting through such Directors, Administrator, or Commissioner, may take such action as may be appropriate to respond to the public health emergency, including making grants and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder described in paragraph (1).

(b)(1) There is established in the Treasury a fund designated the "Public Health Emergency Fund" to be available to the Secretary without fiscal year limitation to carry out subsection (a). There is authorized to be appropriated to the fund \$30,000,000 for fiscal year 1984. For fiscal year 1985 and each fiscal year thereafter there is authorized to be appropriated to the fund such sums as may be necessary to have \$45,000,000 in the fund at the beginning of such fiscal year.

(2) The Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than ninety days after the end of a fiscal year—

(A) on the expenditures made from the Public Health Emergency Fund in such fiscal year; and

(B) describing each public health emergency for which the expenditures were made and the activities undertaken with respect to each emergency which were conducted or supported by expenditures from the Fund.

HANSEN'S DISEASE PROGRAM

SEC. 320. [247e] (a) The Secretary—

(1) shall provide care and treatment (including outpatient care) without charge at the Gillis W. Long Hansen's Disease Center in Carville, Louisiana, to any person suffering from Hansen's disease who needs and requests care and treatment for that disease; and

(2) may provide for the care and treatment (including outpatient care) of Hansen's disease without charge for any person who requests such care and treatment.

(b) The Secretary shall make payments to the Board of Health of Hawaii for the care and treatment (including outpatient care) in its facilities of persons suffering from Hansen's disease at a rate, determined from time to time by the Secretary, which shall, subject to the availability of appropriations, be approximately equal to the operating cost per patient of those facilities, except that the rate determined by the Secretary shall not be greater than the comparable operating cost per Hansen's disease patient at the Gillis W. Long Hansen's Disease Center in Carville, Louisiana.

PART C—HOSPITALS, MEDICAL EXAMINATIONS, AND MEDICAL CARE

HOSPITALS

SEC. 321. [248] The Surgeon General, pursuant to regulations, shall—

(a) Control, manage, and operate all institutions, hospitals, and stations of the Service, including minor repairs and maintenance, and provide for the care, treatment, and hospitalization of patients, including the furnishing of prosthetic and orthopedic devices; and from time to time with the approval of the President, select suitable sites for and establish such additional institutions, hospitals, and stations in the States and possessions of the United States as in his judgment are necessary to enable the Service to discharge its functions and duties;

(b) Provide for the transfer of Public Health Service patients, in the care of attendants where necessary, between hospitals and stations operated by the Service or between such hospitals and stations and other hospitals and stations in which Public Health Service patients may be received, and the payment of expenses of such transfer;

(c) Provide for the disposal of articles produced by patients in the course of their curative treatment, either by allowing the patient to retain such articles or by selling them and depositing the money received therefor to the credit of the appropriation from which the materials for making the articles were purchased;

(d) Provide for the disposal of money and effects, in the custody of the hospitals or stations, of deceased patients; and

(e) Provide, to the extent the Surgeon General determines that other public or private funds are not available therefor, for the payment of expenses of preparing and transporting the remains of, or the payment of reasonable burial expenses for, any patient dying in a hospital or station.

CARE AND TREATMENT OF PERSONS UNDER QUARANTINE AND CERTAIN OTHER PERSONS

SEC. 322. [249] (a) Any person when detained in accordance with quarantine laws, or, at the request of the Immigration and

Naturalization Service, any person detained by that Service, may be treated and cared for by the Public Health Service.

(b) Persons not entitled to treatment and care at institutions, hospitals, and stations of the Service may, in accordance with regulations of the Surgeon General, be admitted thereto for temporary treatment and care in case of emergency.

(c) Persons whose care and treatment is authorized by subsection (a) may, in accordance with regulations, receive such care and treatment at the expense of the Service from public or private medical or hospital facilities other than those of the Service, when authorized by the officer in charge of the station at which the application is made.

CARE AND TREATMENT OF FEDERAL PRISONERS ¹

SEC. 323. [250] The Service shall supervise and furnish medical treatment and other necessary medical, psychiatric, and related technical and scientific services, authorized by the Act of May 13, 1930, as amended (U.S.C., 1940 edition, title 18, secs. 751, 752),² in penal and correctional institutions of the United States.

EXAMINATION AND TREATMENT OF FEDERAL EMPLOYEES

SEC. 324. [251] (a) The Surgeon General is authorized to provide at institutions, hospitals, and stations of the Service medical, surgical, and hospital services and supplies for persons entitled to treatment under the United States Employees' Compensation Act³ and extensions thereof. The Surgeon General may also provide for making medical examinations of—

(1) employees of the Federal Government for retirement purposes;

(2) employees in Federal classified service, and applicants for appointment, as requested by the Civil Service Commission for the purpose of promoting health and efficiency;

(3) seamen for purposes of qualifying for certificates of service; and

(4) employees eligible for benefits under the Longshoremen's and Harbor Workers' Compensation Act, as amended (U.S.C. 1940 edition, title 33, chapter 18),⁴ as requested by any deputy commissioner thereunder.

(b) The Secretary is authorized to provide medical, surgical, and dental treatment and hospitalization and optometric care for Federal employees (as defined in section 8901(1) of title 5 of the United States Code) and their dependents at remote medical facilities of the Public Health Service where such care and treatment are not otherwise available. Such employees and their dependents who are not entitled to this care and treatment under any other

¹ Title I of Public Law 103-317, an appropriations Act regarding certain agencies, provided that of certain amounts "there may be transferred to the Health Resources and Services Administration such amounts as may be necessary, in the discretion of the Attorney General, for direct expenditures by that Administration for medical relief for inmates of Federal penal and correctional institutions" (108 Stat. 1732). Similar provisions have appeared in the analogous appropriations Act of many prior years. See section 250a of title 42, United States Code, and the notes following such section.

² Now codified to section 4005 of title 18, United States Code.

³ Codified to chapter 81 of title 5, United States Code.

⁴ Codification remains chapter 18 of title 33, United States Code.

provision of law shall be charged for it at rates established by the Secretary to reflect the reasonable cost of providing the care and treatment. Any payments pursuant to the preceding sentence shall be credited to the applicable appropriation to the Public Health Service for the year in which such payments are received.

EXAMINATION OF ALIENS

SEC. 325. [252] The Surgeon General shall provide for making, at places within the United States or in other countries, such physical and mental examinations of aliens as are required by the immigration laws, subject to administrative regulations prescribed by the Attorney General and medical regulations prescribed by the Surgeon General with the approval of the Secretary.

SERVICES TO COAST GUARD, COAST AND GEODETIC SURVEY, AND PUBLIC HEALTH SERVICE

SEC. 326. [253] (a) Subject to regulations of the President—

(1) commissioned officers, chief warrant officers, warrant officers, cadets, and enlisted personnel of the Regular Coast Guard on active duty, including those on shore duty and those on detached duty; and Regular and temporary members of the United States Coast Guard Reserve when on active duty;

(2) commissioned officers, ships' officers, and members of the crews of vessels of the United States Coast and Geodetic Survey on active duty including those on shore duty and those on detached duty; and

(3) commissioned officers of the Regular or Reserve Corps of the Public Health Service on active duty;

shall be entitled to medical, surgical, and dental treatment and hospitalization by the Service. The Surgeon General may detail commissioned officers for duty aboard vessels of the Coast Guard or the Coast and Geodetic Survey.

(b)(1) The Secretary may provide health care for an officer of the Regular or Reserve Corps involuntarily separated from the Service, and for any dependent of such officer, if—

(A) the officer or dependent was receiving health care at the expense of the Service at the time of the separation; and

(B) the Secretary finds that the officer or dependent is unable to obtain appropriate insurance for the conditions for which the officer or dependent was receiving health care.

(2) Health care may be provided under paragraph (1) for a period of not more than one year from the date of separation of the officer from the Service.

(c) The Service shall provide all services referred to in subsection (a) required by the Coast Guard or Coast and Geodetic Survey and shall perform all duties prescribed by statute in connection with the examinations to determine physical or mental condition for purposes of appointment, enlistment, and reenlistment, promotion and retirement, and officers of the Service assigned to duty on Coast Guard or Coast and Geodetic Survey vessels may extend aid to the crews of American vessels engaged in deep-sea fishing.

INTERDEPARTMENTAL WORK

SEC. 327. [254] Nothing contained in this part shall affect the authority of the Service to furnish any materials, supplies, or equipment, or perform any work or services, requested in accordance with section 7 of the Act of May 21, 1920, as amended (U.S.C., 1940 edition, title 31, sec. 686), or the authority of any other executive department to furnish any materials, supplies, or equipment, or perform any work or services, requested by the Department of Health, Education, and Welfare for the Service in accordance with that section.

SHARING OF MEDICAL CARE FACILITIES AND RESOURCES

SEC. 327A. [254a] (a) For purposes of this section—

(1) the term “specialized health resources” means health care resources (whether equipment, space, or personnel) which, because of cost, limited availability, or unusual nature, are either unique in the health care community or are subject to maximum utilization only through mutual use;

(2) the term “hospital”, unless otherwise specified, includes (in addition to other hospitals) any Federal hospital.

(b) For the purpose of maintaining or improving the quality of care in Public Health Service facilities and to provide a professional environment therein which will help to attract and retain highly qualified and talented health personnel, to encourage mutually beneficial relationships between Public Health Service facilities and hospitals and other health facilities in the health care community, and to promote the full utilization of hospitals and other health facilities and resources, the Secretary may—

(1) enter into agreements or arrangements with schools of medicine, schools of osteopathic medicine, and with other health professions schools, agencies, or institutions, for such interchange or cooperative use of facilities and services on a reciprocal or reimbursable basis, as will be of benefit to the training or research programs of the participating agencies; and

(2) enter into agreement or arrangements with hospitals and other health care facilities for the mutual use or the exchange of use of specialized health resources, and providing for reciprocal reimbursement.

Any reimbursement pursuant to any such agreement or arrangement shall be based on charges covering the reasonable cost of such utilization, including normal depreciation and amortization costs of equipment. Any proceeds to the Government under this subsection shall be credited to the applicable appropriation of the Public Health Service for the year in which such proceeds are received.

PART D—PRIMARY HEALTH CARE

Subpart I—Primary Health Centers

MIGRANT HEALTH

SEC. 329. [254b] (a) For purposes of this section:

(1) The term "migrant health center" means an entity which either through its staff and supporting resources or through contracts or cooperative arrangements with other public or private entities provides—

(A) primary health services,

(B) as may be appropriate for particular centers, supplemental health services necessary for the adequate support of primary health services,

(C) referral to providers of supplemental health services and payment, as appropriate and feasible, for their provision of such services,

(D) environmental health services, including, as may be appropriate for particular centers (as determined by the centers), the detection and alleviation of unhealthful conditions associated with water supply, sewage treatment, solid waste disposal, rodent and parasitic infestation, field sanitation, housing, and other environmental factors related to health,

(E) as may be appropriate for particular centers (as determined by the centers), infections and parasitic disease screening and control,

(F) as may be appropriate for particular centers, accident prevention programs, including prevention of excessive pesticide exposure,

(G) information on the availability and proper use of health services and services which promote and facilitate optimal use of health services, including, if a substantial number of the individuals in the population served by a center are of limited English-speaking ability, the services of appropriate personnel fluent in the language spoken by a predominant number of such individuals, and

(H) patient case management services (including outreach, counseling, referral, and follow-up services),

for migratory agricultural workers, seasonal agricultural workers, and the members of the families of such migratory and seasonal workers, within the area it serves (referred to in this section as a "catchment area") and individuals who have previously been migratory agricultural workers but can no longer meet the requirements of paragraph (2) of this subsection because of age or disability and members of their families within the area it serves.

(2) The term "migratory agricultural worker" means an individual whose principal employment is in agriculture on a seasonal basis, who has been so employed within the last twenty-four months, and who establishes for the purposes of such employment a temporary abode.

(3) The term "seasonal agricultural workers" means an individual whose principal employment is in agriculture on a seasonal basis and who is not a migratory agricultural worker.

(4) The term "agriculture" means farming in all its branches, including—

(A) cultivation and tillage of the soil,

(B) the production, cultivation, growing, and harvesting of any commodity grown on, in, or as an adjunct to or part of a commodity grown in or on, the land, and

(C) any practice (including preparation and processing for market and delivery to storage or to market or to carriers for transportation to market) performed by a farmer or on a farm incident to or in conjunction with an activity described in subparagraphs (B).

(5) The term "high impact area" means a health service area or other area which has not less than four thousand migratory agricultural workers and seasonal agricultural workers residing within its boundaries for more than two months in any calendar year. In computing the number of workers residing in an area, there shall be included as workers the members of the families of such workers.

(6) The term "primary health services" means—

(A) services of physicians and, where feasible, services of physicians' assistants and nurse clinicians;

(B) diagnostic laboratory and radiologic services;

(C) preventive health services (including children's eye and ear examinations to determine the need for vision and hearing correction, perinatal services, well child services, immunizations against vaccine-preventable diseases, screenings for elevated blood lead levels, and family planning services);

(D) emergency medical services;

(E) transportation services as required for adequate patient care;

(F) preventive dental services; and

(G) pharmaceutical services, as may be appropriate for particular centers.

(7) The term "supplemental health services" means services which are not included as primary health services and which are—

(A) hospital services;

(B) home health services;

(C) extended care facility services;

(D) rehabilitative services (including physical therapy) and long-term physical medicine;

(E) mental health services;

(F) dental services;

(G) vision services;

(H) allied health services;

(I) therapeutic radiologic services;

(J) public health services (including, for the social and other nonmedical needs which affect health status, counseling, referral for assistance, and followup services);

(K) ambulatory surgical services;

(L) health education services (including nutrition education); and

(M) other services appropriate to meet the health needs of the population served by the migrant health center involved.

(b)(1) The Secretary shall assign to high impact areas and any other areas (where appropriate) priorities for the provision of assistance under this section to projects and programs in such areas. The highest priorities for such assistance shall be assigned to areas where the Secretary determines the greatest need exists.

(2) No application for a grant under subsection (c) or (d) for a project in an area which has no migratory agricultural workers

may be approved unless grants have been provided for all approved applications under such subsections for projects in areas with migratory agricultural workers.

(c)(1)(A) The Secretary may, in accordance with the priorities assigned under subsection (b)(1), make grants to public and non-profit private entities for projects to plan and develop migrant health centers which will serve migratory agricultural workers, seasonal agricultural workers, and the members of the families of such migratory and seasonal workers, in high impact areas. A project for which a grant may be made under this subparagraph may include the cost of the acquisition, expansion, and modernization of existing buildings and construction of new buildings (including the costs of amortizing the principal of, and paying the interest on loans) and the costs of providing training related to the management of migrant health center programs, and shall include—

(i) an assessment of the need that the workers (and the members of the families of such workers) proposed to be served by the migrant health center for which the project is undertaken have for primary health services, supplemental health services, and environmental health services;

(ii) the design of a migrant health center program for such workers and the members of their families, based on such assessment;

(iii) efforts to secure, within the proposed catchment area of such center, financial and professional assistance and support for the project; and

(iv) initiation and encouragement of continuing community involvement in the development and operation of the project.

(B) The Secretary may make grants to or enter into contracts with public and nonprofit private entities for projects to plan and develop programs in areas in which no migrant health center exists and in which not more than four thousand migratory agricultural workers and their families reside for more than two months—

(i) for the provision of emergency care to migratory agricultural workers, seasonal agricultural workers, and the members of families of such migratory and seasonal workers;

(ii) for the provision of primary care (as defined in regulations of the Secretary) for such workers and the members of their families;

(iii) for the development of arrangements with existing facilities to provide primary health services (not included as primary care as defined under regulations under clause (ii)) to such workers and the members of their families; or

(iv) which otherwise improve the health of such workers and their families.

Any such program may include the acquisition, expansion, and modernization of existing buildings, construction of new buildings, and providing training related to the management of programs assisted under this subparagraph.

(2) Not more than two grants may be made under paragraph (1)(A) for the same project, and if a grant or contract is made or entered into under paragraph (1)(B) for a project, no other grant or contract under that paragraph may be made or entered into for the project.

(3) The amount of any grant made under paragraph (1) for any project shall be determined by the Secretary.

(d)(1)(A)(i) The Secretary may, in accordance with priorities assigned under subsection (b)(1), make grants for the cost of operation of public and nonprofit private migrant health centers in high impact areas.

(ii) If the Secretary makes a determination that an area is a high impact area, the Secretary may alter the determination only after providing to the grantee under subclause (i) for the area, and to other interested entities in the area, reasonable notice with respect to such determination and a reasonable opportunity to offer information with respect to such determination.

(B) The Secretary may make grants to and enter into contracts with public and nonprofit private entities for projects for the operation of programs in areas in which no migrant health center exists and in which not more than four thousand migratory agricultural workers and their families reside for more than two months—

(i) for the provision of emergency care to migratory agricultural workers, seasonal agricultural workers, and the members of the families of such migratory and seasonal workers;

(ii) for the provision of primary care (as defined in regulations of the Secretary) for such workers and the members of their families;

(iii) for the development of arrangements with existing facilities to provide primary health services (not included as primary care as defined under regulations under clause (ii)) to such workers and the members of their families; or

(iv) which otherwise improve the health of such workers and the members of their families.

Any such program may include the acquisition, expansion, and modernization of existing buildings, construction of new buildings, and providing training related to the management of programs assisted under this subparagraph.

(C) The Secretary may make grants to migrant health centers to enable the centers to plan and develop the provision of health services on a prepaid basis to some or to all of the individuals which the centers serve. Such a grant may only be made for such a center if—

(i) the center has received grants under subparagraph (A) of this paragraph for at least two consecutive years preceding the year of the grant under this subparagraph;

(ii) the governing board of the center (described in subsection (f)(3)(G)) requests, in a manner prescribed by the Secretary, that the center provide health services on a prepaid basis to some or to all of the population which the center serves; and

(iii) the center provides assurances satisfactory to the Secretary that the provision of such services on a prepaid basis will not result in the diminution of health services provided by the center to the population the center served prior to grant under this subparagraph.

Any such grant may include the acquisition, expansion, and modernization of existing buildings, construction of new buildings, and

providing training related to the management of the provision of health services on a prepaid basis.

(2) The costs for which a grant may be made under paragraph (1)(A) may include the costs of acquiring, expanding, and modernizing existing buildings and constructing new buildings (including the costs of amortizing the principal of, and paying the interest on, loans); and the costs of repaying loans made by the Farmers Home Administration for buildings; and the costs for which a grant or contract may be made under paragraph (1) may include the costs of providing training related to the provision of primary health services, supplemental health services, and environmental health services, and to the management of migrant health center programs.

(3) Not more than two grants may be made under paragraph (1)(C) for the same entity.

(4)(A) The amount of any grant made in any fiscal year under subparagraph (A) of paragraph (1) to a health center shall be determined by the Secretary, but may not exceed the amount by which the costs of operation of the center in such fiscal year exceed the total of—

(i) State, local, and other operational funding, and

(ii) the fees, premiums, and third party reimbursements,

which the center may reasonably be expected to receive for its operations in such fiscal year. In determining the amount of such a grant for a center, if the application for the grant requests funds for a service described in subparagraph (D) or (E) of subsection (a)(1) (other than to the extent the funds would be used for the improvement of private property) or a supplemental health service described in subparagraph (B), (F), (J), or (L) of subsection (a)(7), the Secretary shall include, in an amount determined by the Secretary and to the extent funds are available under appropriation Acts, funds for such service unless the Secretary makes a written finding that such service is not needed and provides the applicant with a copy of such finding.

(B) Payments under grants under subparagraph (A) of paragraph (1) shall be made in advance or by way of reimbursement and in such installments as the Secretary finds necessary and adjustments may be made for overpayments or underpayments, except that if in any fiscal year the sum of—

(i) the total of the amounts described in clauses (i) and (ii) of subparagraph (A) of this paragraph received by a center in such fiscal year, and

(ii) the amount of the grant to the center in such fiscal year,

exceeded the costs of the center's operation in such fiscal year because the amount received by the center from fees, premiums, and third-party reimbursements was greater than expected, an adjustment in the amount of the grant to the center in the succeeding fiscal year shall be made in such a manner that the center shall be entitled to retain the additional amount of fees, premiums, and other third party reimbursements as the center will use (I) to expand and improve its services, (II) to increase the number of persons (eligible under subsection (a) to receive services from such a center) it is able to serve, (III) to construct, expand, and modernize

its facilities, (IV) to improve the administration of its service programs, and (V) to establish the financial reserve required for the furnishing of services on a prepaid basis. Without the approval of the Secretary, not more than one-half of such retained sum may be used for construction and modernization of its facilities.

(C) With respect to amounts described in clauses (i) and (ii) of subparagraph (A), the Secretary may not restrict expenditures of such amounts by any grantee under paragraph (1)(A) for—

(i) repair or minor renovation of the physical plant;

(ii) establishment of a financial reserve as required for the furnishing of services on a prepaid basis or as needed to cover unanticipated expenses;

(iii) interest payments on short-term loans to cover cash shortfalls; or

(iv) necessary salary requirements to remain competitive in hiring health care practitioners.

(e) The Secretary may enter into contracts with public and private entities to—

(1) assist the States in the implementation and enforcement of acceptable environmental health standards, including enforcement of standards for sanitation in migrant labor camps and applicable Federal and State pesticide control standards; and

(2) conduct projects and studies to assist the several States and entities which have received grants or contracts under this section in the assessment of problems related to camp and field sanitation, pesticide hazards, and other environmental health hazards to which migratory agricultural workers, seasonal agricultural workers, and members of their families are exposed.

(f)(1) No grant may be made under subsection (c) or (d) and no contract may be entered into under subsection (c)(1)(B), (d)(1)(B), or (e) unless an application therefor is submitted to, and approved by, the Secretary. Such an application shall be submitted in such form and manner and shall contain such information as the Secretary shall prescribe. An application for a grant or contract which will cover the costs of modernizing a building shall include, in addition to other information required by the Secretary—

(A) a description of the site of the building,

(B) plans and specifications for its modernization, and

(C) reasonable assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of work on the modernization of the building will be paid wages at rates not less than those prevailing on similar work in the locality as determined by the Secretary of Labor in accordance with the Act of March 3, 1931 (40 U.S.C. 276a—276a-5, known as the Davis-Bacon Act).

The Secretary of Labor shall have with respect to the labor standards referred to in subparagraph (C) the authority and functions set forth in Reorganization Plan Numbered 74 of 1950 (15 F.R. 3176; 5 U.S.C. Appendix) and section 2 of the Act of June 13, 1934 (40 U.S.C. 276c).

(2) An application for a grant under subparagraph (A) of subsection (d)(1) for a migrant health center shall include—

(A) a description of the need in the center's catchment area for each of the health services described in subparagraph (D) and (E) of subsection (a)(1) and in subparagraphs (B), (F), (J), and (L) of subsection (a)(7),

(B) if the applicant determines that any such service is not needed, the basis for such determination, and

(C) if the applicant does not request funds for any such service which the applicant determines is needed, the reason for not making such a request.

In considering an application for a grant under subparagraph (A) of subsection (d)(1), the Secretary may require as a condition to the approval of such application assurance that the applicant will provide any specified health service described in subsection (a) which the Secretary finds is needed to meet specific health needs of the area to be served by the applicant. Such a finding shall be made in writing and a copy shall be provided the applicant.

(3) The Secretary may not approve an application for a grant under subsection (d)(1)(A) unless the Secretary determines that the entity for which the application is submitted is a migrant health center (within the meaning of subsection (a)(1)) and that—

(A) the primary health services of the center will be available and accessible in the center's catchment area promptly, as appropriate, and in a manner which assures continuity;

(B) the center will have organizational arrangements, established in accordance with regulations of the Secretary, for (i) an ongoing quality assurance program (including utilization and peer review systems) respecting the center's services, and (ii) maintaining the confidentiality of patient records;

(C) the center will demonstrate its financial responsibility by the use of such accounting procedures and other requirements as may be prescribed by the Secretary;

(D) the center (i) has or will have a contractual or other arrangement with the agency of the State, in which it provides services, which administers or supervises the administration of a State plan approved under title XIX of the Social Security Act for the payment of all or a part of the center's costs in providing health services to persons who are eligible for medical assistance under such a State plan, or (ii) has made or will make every reasonable effort to enter into such arrangement;

(E) the center has made or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under title XVIII of the Social Security Act, to medical assistance under a State plan approved under title XIX of such Act, or to assistance for medical expenses under any other public assistance program or private health insurance program;

(F) the center (i) has prepared a schedule of fees or payments for the provision of its services consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation and has prepared a corresponding schedule of discounts to be applied to the payment of such fees or payments, which discounts are adjusted on the basis of the patient's ability to pay, (ii) has made and will continue to make

every reasonable effort (I) to secure from patients payment for services in accordance with such schedules, and (II) to collect reimbursement for health services to persons described in subparagraph (E) on the basis of the full amount of fees and payments for such services without application of any discount, and (iii) has submitted to the Secretary such reports as he may require to determine compliance with this subparagraph;

(G) the center has established a governing board which (i) is composed of individuals, a majority of whom are being served by the center and who, as a group, represent the individuals being served by the center, and (ii) selects the services to be provided by the center, schedules the hours during which such services will be provided, approves the center's annual budget, approves the selection of a director for the center, and, except in the case of a public center (as defined in the second sentence of this paragraph), establishes general policies for the center; and if the application is for a second or subsequent grant for a public center, the governing body of the center has approved the application or if the governing body has not approved the application, the failure of the governing body to approve the application was unreasonable;

(H) the center has developed, in accordance with regulations of the Secretary, (i) an overall plan and budget that meets the requirements of section 1861(z) of the Social Security Act, and (ii) an effective procedure for compiling and reporting to the Secretary such statistics and other information as the Secretary may require relating to (I) the costs of its operations, (II) the patterns of use of its services, (III) the availability, accessibility, and acceptability of its services, (IV) such other matters relating to operations of the applicant as the Secretary may, by regulation, require, and (V) expenditures made from any amount the center was permitted to retain under subsection (d)(4)(B);

(I) the center will review periodically its catchment area to (i) insure that the size of such area is such that the services to be provided through the center (including any satellite) are available and accessible to the migratory agricultural workers, seasonal agricultural workers, and the members of the families of such migratory and seasonal workers, in the area promptly and as appropriate, (ii) insure that the boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and Federal and State health and social service programs, and (iii) insure that the boundaries of such area eliminate, to the extent possible, barriers to access to the services of the center, including barriers resulting from the area's physical characteristics, its residential patterns, its economic and social groupings, and available transportation; and

(J) in the case of a center which serves a population including a substantial proportion of individuals of limited English-speaking ability, the center has (i) developed a plan and made arrangements responsive to the needs of such population for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and

(ii) identified an individual on its staff who is fluent in both that language and English and whose responsibilities shall include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences.

For purposes of subparagraph (G) and subsection (h)(4), the term "public center" means a migrant health center funded (or to be funded) through a grant under this section to a public agency.

(4) In considering applications for grants and contracts under subsection (c) or (d)(1)(B), the Secretary shall give priority to applications submitted by community-based organizations which are representative of the populations to be served through the projects, programs, or centers to be assisted by such grants or contracts.

(5) The Secretary, in making a grant under this section to a migrant health center for the provision of environmental health services described in subsection (a)(1)(D), may designate a portion of the grant to be expended for improvements to private property for which the written consent of the owner has been obtained and which are necessary to alleviate a hazard to the health of those residing on, or otherwise using, the property and of other persons in the center's catchment area. A center may make such an expenditure for an improvement under a grant only after the Secretary has specifically approved such expenditure and has determined that funds for the improvement are not available from any other source.

(6) Contracts may be entered into under this section without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529;¹ 41 U.S.C. 5).

(7) The Secretary may make a grant under subsection (c) or (d) for the construction of new buildings for a migrant health center or a migrant health program only if the Secretary determines that appropriate facilities are not available through acquiring, modernizing, or expanding existing buildings and that the entity to which the grant will be made has made reasonable efforts to secure from other sources funds, in lieu of the grant, to construct such facilities.

(g)(1) The Secretary may provide (either through the Department of Health, Education, and Welfare or by grant or contract) all necessary technical and other nonfinancial assistance (including fiscal and program management assistance and training in such management) to any migrant health center or to any public or private nonprofit entity to assist it in developing plans for, and in operating as, a migrant health center, and in meeting the requirements of subsection (f)(2).

(2) The Secretary shall make available to each grant recipient under this section a list of available Federal and non-Federal resources to improve the environmental and nutritional status of individuals in the recipient's catchment area.

(h)(1)(A) For the purposes of subsections (c) through (e), there are authorized to be appropriated \$48,500,000 for fiscal year 1989, such sums as may be necessary for fiscal years 1990 and 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1994.

¹Now codified to section 3324 of title 31, United States Code.

(B) Of the amounts appropriated pursuant to subparagraph (A) for a fiscal year, the Secretary may obligate for grants and contracts under subsection (c)(1) not more than 2 percent, for grants under subsection (d)(1)(C) not more than 5 percent, and for contracts under subsection (e) not more than 10 percent.

(2)(A) For the purpose of carrying out subparagraph (B), there are authorized to be appropriated \$1,500,000 for fiscal year 1989, \$2,000,000 for fiscal year 1990, \$2,500,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1994.

(B) The Secretary may make grants to migrant health centers for the purpose of assisting such centers in—

(i) providing comprehensive health care and support services for the reduction of (I) the incidence of infant mortality, and (II) morbidity among children who are less than 3 years of age; and

(ii) developing and coordinating service and referral arrangements between migrant health centers and other entities for the health management of pregnant women and children described in clause (i).

(C) In making grants under subparagraph (B), the Secretary shall give priority to migrant health centers providing services in any catchment area in which there is a substantial incidence of infant mortality or in which there is a significant increase in the incidence of infant mortality.

(D) The Secretary may make a grant under subparagraph (B) only if the migrant health center involved agrees to expend the grant for the following activities with respect to the purpose described in such subparagraph:

(i) Primary health services, including prenatal care.

(ii) Community education, outreach, and case finding.

(iii) Case management services.

(iv) Client education, including parenting and child development education.

(E) The purposes for which a migrant health center may expend a grant under subparagraph (B) include, with respect to the purpose described in such subparagraph, substance abuse screening, counseling and referral services, and other necessary nonmedical support services, including child care, translation services, and housing assistance.

(F) The Secretary may make a grant under subparagraph (B) only if the migrant health center involved agrees that—

(i) the center will coordinate the provision of services under the grant to each of the recipients of the services;

(ii) such services will be continuous for each such recipient;

(iii) the center will provide follow-up services for individuals who are referred by the center for services described in subparagraph (E); and

(iv) the grant will be expended to supplement, and not supplant, the expenditures of the center for primary health services (including prenatal care) with respect to the purpose described in such subparagraph.

(3) The Secretary may not expend in any fiscal year, for grants under this section to public centers (as defined in the second sen-

tence of subsection (f)(3)) the governing boards of which (as described in subsection (f)(3)(G)(ii)) do not establish general policies for such centers, an amount which exceeds 5 per centum of the funds appropriated under this section for that fiscal year.

(i) The Secretary may delegate the authority to administer the programs authorized by this section to any office within the Service, except that the authority to enter into, modify, or issue approvals with respect to grants or contracts may be delegated only within the central office of the Health Resources and Services Administration.

COMMUNITY HEALTH CENTERS

SEC. 330. [254c] (a) For purposes of this section, the term "community health center" means an entity which either through its staff and supporting resources or through contacts or cooperative arrangements with other public or private entities provides—

(1) primary health services,

(2) as may be appropriate for particular centers, supplemental health services necessary for the adequate support of primary health services,

(3) referral to providers of supplemental health services and payment, as appropriate and feasible, for their provision of such services,

(4) environmental health services, including, as may be appropriate for particular centers (as determined by the centers), the detection and alleviation of unhealthful conditions associated with water supply, sewage treatment, solid waste disposal, rodent and parasitic infestation, field sanitation, housing, and other environmental factors related to health,

(5) information on the availability and proper use of health services and services which promote and facilitate optimal use of health services, including, if a substantial number of the individuals in the population served by a center are of limited English-speaking ability, the services of appropriate personnel fluent in the language spoken by a predominant number of such individuals, and

(6) patient case management services (including outreach, counseling, referral, and follow-up services),

for all residents of the area it serves (referred to in this section as a "catchment area").

(b) For purposes of this section:

(1) The term "primary health services" means—

(A) services of physicians and, where feasible, services of physicians' assistants and nurse clinicians;

(B) diagnostic laboratory and radiologic services;

(C) preventive health services (including children's eye and ear examinations to determine the need for vision and hearing correction, perinatal services, well child services, immunizations against vaccine-preventable diseases, screenings for elevated blood lead levels, and family planning services);

(D) emergency medical services;

(E) transportation services as required for adequate patient care;

(F) preventive dental services; and

(G) pharmaceutical services, as may be appropriate for particular centers.

(2) The term "supplemental health services" means services which are not included as primary health services and which are—

(A) hospital services;

(B) home health services;

(C) extended care facility services;

(D) rehabilitative services (including physical therapy) and long-term physical medicine;

(E) mental health services;

(F) dental services;

(G) vision services;

(H) allied health services;

(I) therapeutic radiologic services;

(J) public health services (including, for the social and other nonmedical needs which affect health status, counseling, referral for assistance, and followup services);

(K) ambulatory surgical services;

(L) health education services (including nutrition education); and

(M) other services appropriate to meet the health needs of the medically underserved population served by the community health center involved.

(3) The term "medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services.

(4) In carrying out paragraph (3), the Secretary shall by regulation prescribe criteria for determining the specific shortages of personal health services of an area or population group. Such criteria shall—

(A) take into account comments received by the Secretary from the chief executive officer of a State and local officials in a State; and

(B) include infant mortality in an area or population group, other factors indicative of the health status of a population group or residents of an area, the ability of the residents of an area or of a population group to pay for health services and their accessibility to them, and the availability of health professionals to residents of an area or to a population group. The Secretary may modify the criteria established in regulations issued under this paragraph only after affording public notice and an opportunity for comment on any such proposed modifications.

(5) The Secretary may not designate a medically underserved population in a State or terminate the designation of such a population unless, prior to such designation or termination, the Secretary provides reasonable notice and opportunity for comment and consults with—

(A) the chief executive officer of such State;

(B) local officials in such State; and

(C) the State organization, if any, which represents a majority of community health centers in such State.

(6) The Secretary may designate a medically underserved population that does not meet the criteria established under paragraph (4) if the chief executive officer of the State in which such population is located and local officials of such State recommend the designation of such population based on unusual local conditions which are a barrier to access to or the availability of personal health services.

(c)(1) The Secretary may make grants to public and nonprofit private entities for projects to plan and develop community health centers which will serve medically underserved populations. A project for which a grant may be made under this subsection may include the cost of the acquisition, expansion, and modernization of existing buildings and construction of new buildings (including the costs of amortizing the principal of, and paying the interest on, loans) and shall include—

(A) an assessment of the need that the population proposed to be served by the community health center for which the project is undertaken has for primary health services, supplemental health services, and environmental health services;

(B) the design of a community health center program for such population based on such assessment;

(C) efforts to secure, within the proposed catchment area of such center, financial and professional assistance and support for the project; and

(D) initiation and encouragement of continuing community involvement in the development and operation of the project.

(2) Not more than two grants may be made under this subsection for the same project.

(3) The amount of any grant made under this subsection for any project shall be determined by the Secretary.

(d)(1)(A) The Secretary may make grants for the costs of operation of public and nonprofit private community health centers which serve medically underserved populations.

(B) The Secretary may make grants for the costs of the operation of public and nonprofit private entities which provide health services to medically underserved populations but with respect to which he is unable to make each of the determinations required by subsection (e)(3).

(C) The Secretary may make grants to community health centers to enable the centers to plan and develop the provision of health services on a prepaid basis to some or to all of the individuals which the centers serve. Such a grant may only be made for such a center if—

(i) the center has received grants under subparagraph (A) of this paragraph for at least two consecutive years preceding the year of the grant under this subparagraph;

(ii) the governing board of the center (described in subsection (e)(3)(G)) requests, in a manner prescribed by the Secretary, that the center provide health services on a prepaid basis to some or to all of the population which the center serves; and

(iii) the center provides assurances satisfactory to the Secretary that the provision of such services on a prepaid basis will not result in the diminution of health services provided by

the center to the population the center served prior to the grant under this subparagraph.

Any such grant may include the acquisition, expansion, and modernization of existing buildings, construction of new buildings, and providing training related to management on the provision of health services on a prepaid basis.

(2) The costs for which a grant may be made under paragraph (1)(A) or (1)(B) may include the costs of acquiring, expanding, and modernizing existing buildings and constructing new buildings (including the costs of amortizing the principal of, and paying interest on, loans), the costs of repaying loans made by the Farmers Home Administration for buildings, and the costs of providing training related to the provision of primary health services, supplemental health services and environmental health services, and to the management of community health center programs.

(3) Not more than two grants may be made under paragraph (1)(B) or (1)(C) for the same entity.

(4)(A) The amount of any grant made in any fiscal year under paragraph (1) (other than subparagraph (C)) to a community health center shall be determined by the Secretary, but may not exceed the amount by which the costs of operation of the center in such fiscal year exceed the total of—

(i) State, local, and other operational funding, and

(ii) the fees, premiums, and third-party reimbursements, which the center may reasonably be expected to receive for its operations in such fiscal year. In determining the amount of such a grant for a center, if the application for the grant requests funds for a service described in subsection (a)(4) (other than to the extent the funds would be used for the improvement of private property) or a supplemental health service described in subparagraph (B), (F), (L), or (M) of subsection (b)(2), the Secretary shall include, in an amount determined by the Secretary and to the extent funds are available under appropriation Acts, funds for such service unless the Secretary makes a written finding that such service is not needed and provides the applicant with a copy of such finding.

(B) Payments under grants under subparagraph (A) or (B) of paragraph (1) shall be made in advance or by way of reimbursement and in such installments as the Secretary finds necessary and adjustments may be made for overpayments or underpayments, except that if in any fiscal year the sum of—

(i) the total of the amounts described in clauses (i) and (ii) of subparagraph (A) received by a center in such fiscal year, and

(ii) the amount of the grant to the center in such fiscal year,

exceeded the costs of the center's operation in such fiscal year because the amount received by the center from fees, premiums, and third-party reimbursements was greater than expected, an adjustment in the amount of the grant to the center in the succeeding fiscal year shall be made in such a manner that the center shall be entitled to retain the additional amount of fees, premiums, and other third party reimbursements as the center will use (I) to expand and improve its services, (II) to increase the number of per-

sons (eligible to receive services from such a center) it is able to serve, (III) to construct, expand, and modernize its facilities, (IV) to improve the administration of its service programs, and (V) to establish the financial reserve required for the furnishing of services on a prepaid basis. Without the approval of the Secretary, not more than one-half of such retained sum may be used for construction and modernization of its facilities.

(C) With respect to amounts described in clauses (i) and (ii) of subparagraph (A), the Secretary may not restrict expenditures of such amounts by any grantee under paragraph (1) for—

(i) repair or minor renovation of the physical plant;

(ii) establishment of a financial reserve as required for the furnishing of services on a prepaid basis or as needed to cover unanticipated expenses;

(iii) interest payments on short-term loans to cover cash shortfalls; or

(iv) necessary salary requirements to remain competitive in hiring health care practitioners.

(e)(1) No grant may be made under subsection (c) or (d) unless an application therefor is submitted to, and approved by, the Secretary. Such an application shall be submitted in such form and manner and shall contain such information as the Secretary shall prescribe. An application for a grant which will cover the costs of modernizing a building shall include, in addition to other information required by the Secretary—

(A) a description of the site of the building,

(B) plans and specifications for its modernization, and

(C) reasonable assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of work on the modernization of the building will be paid wages at rates not less than those prevailing on similar work in the locality as determined by the Secretary of Labor in accordance with the Act of March 3, 1931 (40 U.S.C. 276a—276a-5, known as the Davis-Bacon Act).

The Secretary of Labor shall have with respect to the labor standards referred to in subparagraph (C) the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 F.R. 3176, 5 U.S.C. Appendix) and section 2 of the Act of June 13, 1934 (40 U.S.C. 276c).

(2) An application for a grant under subparagraph (A) or (B) of subsection (d)(1) for a community health center shall include—

(A) a description of the need in the center's catchment area for each of the health services described in subsection (a)(4) and in subparagraphs (B), (F), (L), and (M) of subsection (b)(2),

(B) if the applicant determines that any such service is not needed, the basis for such determination, and

(C) if the applicant does not request funds for any such service which the applicant determines is needed, the reason for not making such a request.

Such an application shall also include a demonstration by the applicant that the area or a population group to be served by the applicant has a shortage of personal health services and that the center will be located so that it will provide services to the greatest number of persons residing in such area or included in such popu-

lation group. Such a demonstration shall be made on the basis of the criteria prescribed by the Secretary under subsection (b)(3) or on any other criteria which the Secretary may prescribe to determine if the area or population group to be served by the applicant has a shortage of personal health services. In considering an application for a grant under subparagraph (A) or (B) of subsection (d)(1), the Secretary may require as a condition to the approval of such application assurance that the applicant will provide any specified health services described in subsection (a) or (b) which the Secretary finds is needed to meet specific health needs of the area to be served by the applicant. Such a finding shall be made in writing and a copy shall be provided by the applicant.

(3) Except as provided in subsection (d)(1)(B), the Secretary may not approve an application for a grant under paragraph (1)(A) or (1)(B) of subsection (d) unless the Secretary determines that the entity for which the application is submitted is a community health center (within the meaning of subsection (a)) and that—

(A) the primary health services of the center will be available and accessible in the center's catchment area promptly, as appropriate, and in a manner which assures continuity;

(B) the center will have organizational arrangements, established in accordance with regulations prescribed by the Secretary, or (i) an ongoing quality assurance program (including utilization and peer review systems) respecting the center's services, and (ii) maintaining the confidentiality of patient records;

(C) the center will demonstrate its financial responsibility by the use of such accounting procedures and other requirements as may be prescribed by the Secretary;

(D) the center (i) has or will have a contractual or other arrangement with the agency of the State, in which it provides services, which administers or supervises the administration of a State plan approved under title XIX of the Social Security Act for the payment of all or a part of the center's costs in providing health services to persons who are eligible for medical assistance under such a State plan, or (ii) has made or will make every reasonable effort to enter into such an arrangement;

(E) the center has made or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under title XVIII of the Social Security Act, to medical assistance under a State plan approved under title XIX of such Act, or to assistance for medical expenses under any other public assistance program or private health insurance program;

(F) the center (i) has prepared a schedule of fees or payments for the provision of its services consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation and has prepared a corresponding schedule of discounts to be applied to the payment of such fees or payments, which discounts are adjusted on the basis of the patient's ability to pay, (ii) has made and will continue to make every reasonable effort (I) to secure from patients payment for

services in accordance with such schedules, and (II) to collect reimbursement for health services to persons described in subparagraph (E) on the basis of the full amount of fees and payments for such services without application of any discount, and (iii) has submitted to the Secretary such reports as he may require to determine compliance with this subparagraph;

(G) the center has established a governing board which (i) except in the case of an entity operated by an Indian tribe or tribal or Indian organization under the Indian Self-Determination Act, is composed of individuals, a majority of whom are being served by the center and who, as a group, represent the individuals being served by the center, and (ii) meets at least once a month, selects the services to be provided by the center, schedules the hours during which such services will be provided, approves the center's annual budget, approves the selection of a director for the center, and, except in the case of a governing board of a public center (as defined in the second sentence of this paragraph), establishes general policies for the center; and if the application is for a second or subsequent grant for a public center, the governing body has approved the application or if the governing body has not approved the application, the failure of the governing body to approve the application was unreasonable;

(H) the center has developed, in accordance with regulations of the Secretary, (i) an overall plan and budget that meets the requirements of section 1861(z) of the Social Security Act, and (ii) an effective procedure for compiling and reporting to the Secretary such statistics and other information as the Secretary may require relating to (I) the costs of its operations, (II) the patterns of use of its services, (III) the availability, accessibility, and acceptability of its services, (IV) such other matters relating to operations of the applicant as the Secretary may, by regulation, require, and (V) expenditures made from any amount the center was permitted to retain under subsection (d)(4)(B);

(I) the center will review periodically its catchment area to (i) insure that the size of such area is such that the services to be provided through the center (including any satellite) are available and accessible to the residents of the area promptly and as appropriate, (ii) insure that the boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and Federal and State health and social service programs, and (iii) insure that the boundaries of such area eliminate, to the extent possible, barriers to access to the services of the center, including barriers resulting from the area's physical characteristics, its residential patterns, its economic and social grouping, and available transportation;

(J) in the case of a center which serves a population including a substantial proportion of individuals of limited English-speaking ability, the center has (i) developed a plan and made arrangements responsive to the needs of such population for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and

(ii) identified an individual on its staff who is fluent in both that language and in English and whose responsibilities shall include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences; and

(K) the center, in accordance with regulations prescribed by the Secretary, has developed an ongoing referral relationship with one or more hospitals.

For purposes of subparagraph (G) and subsection (g)(4), the term "public center" means a community health center funded (or to be funded) through a grant under this section to a public agency.

(4) The Secretary shall approve applications for grants under paragraph (1)(A) or (1)(B) of subsection (d) for community health centers which—

(A) have not received a previous grant under such paragraph, or

(B) have applied for such a grant to expand their services, in such a manner that the ratio of the medical underserved populations in rural areas which may be expected to use the services provided by such centers to the medical underserved populations in urban areas which may be expected to use the services provided by such centers is not less than two to three or greater than three to two.

(5) The Secretary, in making a grant under this section to a community health center for the provision of environmental health services described in subsection (a)(4), may designate a portion of the grant to be expended for improvements to private property for which the written consent of the owner has been obtained and which are necessary to alleviate a hazard to the health of those residing on, or otherwise using, the property and of other persons in the center's catchment area. A center may make such an expenditure for an improvement under a grant only after the Secretary has specifically approved such expenditure and has determined that funds for the improvement are not available from any other source.

(6) The Secretary may make a grant under subsection (c) or (d) for the construction of new buildings for a community health center only if the Secretary determines that appropriate facilities are not available through acquiring, modernizing, or expanding existing buildings and that the entity to which the grant will be made has made reasonable efforts to secure from other sources funds, in lieu of the grant, to construct such facilities.

(f)(1) The Secretary may provide (either through the Department of Health, Education, and Welfare or by grant or contract) all necessary technical and other nonfinancial assistance (including fiscal and program management assistance and training in such management) to any public or private nonprofit entity to assist it in developing plans for, and in operating as, a community health center, and in meeting requirements of subsection (e)(2).

(2) The Secretary shall make available to each grant recipient under this section a list of available Federal and non-Federal resources to improve the environmental and nutritional status of individuals in the recipient's catchment area.

(g)(1)(A) For the purpose of payments under grants under this section, there are authorized to be appropriated \$440,000,000 for

fiscal year 1989, such sums as may be necessary for fiscal years 1990 and 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1994.

(B) The Secretary may not in any fiscal year—

(i) expend for grants to serve medically underserved populations designated under subsection (b)(6) an amount which exceeds 5 percent of the funds appropriated under paragraph (1) for that fiscal year; and

(ii) expend for grants under subsection (d)(1)(C) an amount which exceeds 5 percent of the funds appropriated under paragraph (1) for that fiscal year.

(2)(A) For the purpose of carrying out subparagraph (B), there are authorized to be appropriated \$25,000,000 for fiscal year 1989, \$30,000,000 for fiscal year 1990, \$35,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1994.

(B) The Secretary may make grants to community health centers for the purpose of assisting such centers in—

(i) providing comprehensive health care and support services for the reduction of (I) the incidence of infant mortality, and (II) morbidity among children who are less than 3 years of age; and

(ii) developing and coordinating service and referral arrangements between community health centers and other entities for the health management of pregnant women and children described in clause (i).

(C) In making grants under subparagraph (B), the Secretary shall give priority to community health centers providing services to any medically underserved population among which there is a substantial incidence of infant mortality or among which there is a significant increase in the incidence of infant mortality.

(D) The Secretary may make a grant under subparagraph (B) only if the community health center involved agrees to expend the grant for the following activities with respect to the purpose described in such subparagraph:

(i) Primary health services, including prenatal care.

(ii) Community education, outreach, and case finding.

(iii) Case management services.

(iv) Client education, including parenting and child development education.

(E) The purposes for which a community health center may expend a grant under subparagraph (B) include, with respect to the purpose described in such subparagraph, substance abuse screening, counseling and referral services, and other necessary nonmedical support services, including child care, translation services, and housing assistance.

(F) The Secretary may make a grant under subparagraph (B) only if the community health center involved agrees that—

(i) the center will coordinate the provision of services under the grant to each of the recipients of the services;

(ii) such services will be continuous for each such recipient;

(iii) the center will provide follow-up services for individuals who are referred by the center for services described in subparagraph (E); and

(iv) the grant will be expended to supplement, and not supplant, the expenditures of the center for primary health services (including prenatal care) with respect to the purpose described in such subparagraph.

(3) The Secretary may not expend in any fiscal year, for grants under this section to public centers (as defined in the second sentence of subsection (e)(3)) the governing boards of which (as described in subsection (e)(3)(G)(ii)) do not establish general policies for such centers, an amount which exceeds 5 per centum of the funds appropriated under this section for that fiscal year.

(h) In carrying out this section, the Secretary may enter into a memorandum of agreement with a State. Such memorandum may include, where appropriate, provisions permitting such State to—

(1) analyze the need for primary health services for medically underserved populations within such State;

(2) assist in the planning and development of new community health centers;

(3) review and comment upon annual program plans and budgets of community health centers, including comments upon allocations of health care resources in the State;

(4) assist community health centers in the development of clinical practices and fiscal and administrative systems through a technical assistance plan which is responsive to the requests of community health centers; and

(5) share information and data relevant to the operation of new and existing community health centers.

(i)(1) Each entity which receives a grant under subsection (d) shall provide for an independent annual financial audit of any books, accounts, financial records, files, and other papers and property which relate to the disposition or use of the funds received under such grant and such other funds received by or allocated to the project for which such grant was made. For purposes of assuring accurate, current, and complete disclosure of the disposition or use of the funds received, each such audit shall be conducted in accordance with generally accepted accounting principles. Each audit shall evaluate—

(A) the entity's implementation of the guidelines established by the Secretary respecting cost accounting,

(B) the processes used by the entity to meet the financial and program reporting requirements of the Secretary, and

(C) the billing and collection procedures of the entity and the relation of the procedures to its fee schedule and schedule of discounts and to the availability of health insurance and public programs to pay for the health services it provides.

A report of each such audit shall be filed with the Secretary at such time and in such manner as the Secretary may require.

(2) Each entity which receives a grant under subsection (d) shall establish and maintain such records as the Secretary shall by regulation require to facilitate the audit required by paragraph (1). The Secretary may specify by regulation the form and manner in which such records shall be established and maintained.

(3) Each entity which is required to establish and maintain records or to provide for and audit under this subsection shall

make such books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying or mechanical reproduction on or off the premises of such entity upon a reasonable request therefor. The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have the authority to conduct such examination, copying, and reproduction.

(4) The Secretary may, under appropriate circumstances, waive the application of all or part of the requirements of this subsection to a community health center.

(j) The Secretary may delegate the authority to administer the programs authorized by this section to any office within the Service, except that the authority to enter into, modify, or issue approvals with respect to grants or contracts may be delegated only within the central office of the Health Resources and Services Administration.

(k) In making grants under this section, the Secretary shall give special consideration to the unique needs of frontier areas.

Subpart II—National Health Service Corps Program

NATIONAL HEALTH SERVICE CORPS

SEC. 331. [254d] (a)(1) For the purpose of eliminating health manpower¹ shortages in health professional shortage areas, there is established, within the Service, the National Health Service Corps, which shall consist of—

(A) such officers of the Regular and Reserve Corps of the Service as the Secretary may designate,

(B) such civilian employees of the United States as the Secretary may appoint, and

(C) such other individuals who are not employees of the United States.

(2) The Corps shall be utilized by the Secretary to provide primary health services in health professional shortage areas.

(3) For purposes of this subpart and subpart III:

(A) The term "Corps" means the National Health Service Corps.

(B) The term "Corps member" means each of the officers, employees, and individuals of which the Corps consists pursuant to paragraph (1).

(C) The term "health professional shortage area" has the meaning given such term in section 332(a).

(D) The term "primary health services" means health services regarding family medicine, internal medicine, pediatrics, obstetrics and gynecology, dentistry, or mental health, that are provided by physicians or other health professionals.

(b)(1) The Secretary may conduct at schools of medicine, osteopathic medicine, dentistry, and, as appropriate, nursing and other schools of the health professions and at entities which train allied health personnel, recruiting programs for the Corps, the Scholar-

¹ So in original. Probably should be "health professional shortages". See section 401(b)(2) of Public Law 101-597 (the first subsection (b)).

ship Program, and the Loan Repayment Program. Such recruiting programs shall include efforts to recruit individuals who will serve in the Corps other than pursuant to obligated service under the Scholarship or Loan Repayment Program.

(2) In the case of physicians, dentists, certified nurse midwives, certified nurse practitioners, and physician assistants who have an interest and a commitment to providing primary health care, the Secretary may establish fellowship programs to enable such health professionals to gain exposure to and expertise in the delivery of primary health services in health professional shortage areas. To the maximum extent practicable, the Secretary shall ensure that any such programs are established in conjunction with accredited residency programs, and other training programs, regarding such health professions.

(c) The Secretary may reimburse applicants for positions in the Corps (including individuals considering entering into a written agreement pursuant to section 338D) for actual and reasonable expenses incurred in traveling to and from their places of residence to a health professional shortage area (designated under section 332) in which they may be assigned for the purpose of evaluating such area with regard to being assigned in such area. The Secretary shall not reimburse an applicant for more than one such trip.

(d)(1) The Secretary may, under regulations promulgated by the Secretary, adjust the monthly pay of each member of the Corps (other than a member described in subsection (a)(1)(C)) who is directly engaged in the delivery of health services in a health professional shortage area as follows:

(A) During the first 36 months in which such a member is so engaged in the delivery of health services, his monthly pay may be increased by an amount which when added to the member's monthly pay and allowances will provide a monthly income competitive with the average monthly income from a practice of an individual who is a member of the profession of the Corps member, who has equivalent training, and who has been in practice for a period equivalent to the period during which the Corps member has been in practice.

(B) During the period beginning upon the expiration of the 36 months referred to in subparagraph (A) and ending with the month in which the member's monthly pay and allowances are equal to or exceed the monthly income he received for the last of such 36 months, the member may receive in addition to his monthly pay and allowances an amount which when added to such monthly pay and allowances equals the monthly income he received for such last month.

(C) For each month in which a member is directly engaged in the delivery of health services in a health professional shortage area in accordance with an agreement with the Secretary entered into under section 741(f)(1)(C), under which the Secretary is obligated to make payments in accordance with section 741(f)(2), the amount of any monthly increase under subparagraph (A) or (B) with respect to such member shall be decreased by an amount equal to one-twelfth of the amount

which the Secretary is obligated to pay upon the completion of the year of practice in which such month occurs.

For purposes of subparagraphs (A) and (B), the term "monthly pay" includes special pay received under chapter 5 of title 37 of the United States Code.

(2) In the case of a member of the Corps who is directly engaged in the delivery of health services in a health professional shortage area in accordance with a service obligation incurred under the Scholarship Program or the Loan Repayment Program, the adjustment in pay authorized by paragraph (1) may be made for such a member only upon satisfactory completion of such service obligation, and the first 36 months of such member's being so engaged in the delivery of health services shall, for purposes of paragraph (1)(A), be deemed to begin upon such satisfactory completion.

(3) A member of the Corps described in subparagraph (C) of subsection (a)(1) shall when assigned to an entity under section 333 be subject to the personnel system of such entity, except that such member shall receive during the period of assignment the income that the member would receive if the member was a member of the Corps described in subparagraph (B) of such subsection.

(e) Corps members assigned under section 333 to provide health services in health professional shortage areas shall not be counted against any employment ceiling affecting the Department.

(f) Sections 214 and 216 shall not apply to members of the National Health Service Corps during their period of obligated service under the Scholarship Program or the Loan Repayment Program.

(g)(1) The Secretary shall, by rule, prescribe conversion provisions applicable to any individual who, within a year after completion of service as a member of the Corps described in subsection (a)(1)(C), becomes a commissioned officer in the Regular or Reserve Corps of the Service.

(2) The rules prescribed under paragraph (1) shall provide that in applying the appropriate provisions of this Act which relate to retirement, any individual who becomes such an officer shall be entitled to have credit for any period of service as a member of the Corps described in subsection (a)(1)(C).

(h) The Secretary shall ensure that adequate staff is provided to the Service with respect to effectively administering the program for the Corps.

(i) For the purposes of this subpart and subpart III:

(1) The term "Department" means the Department of Health and Human Services.

(2) The term "Loan Repayment Program" means the National Health Service Corps Loan Repayment Program established under section 338B.

(3) The term "Scholarship Program" means the National Health Service Corps Scholarship Program established under section 338A.

(4) The term "State" includes, in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

DESIGNATION OF HEALTH PROFESSIONAL SHORTAGE AREAS

SEC. 332. [254e] (a)(1) For purposes of this subpart the term "health professional shortage area" means (A) an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary determines has a health manpower shortage, (B) a population group which the Secretary determines has such a shortage, or (C) a public or nonprofit private medical facility or other public facility which the Secretary determines has such a shortage. The Secretary shall not remove an area from the areas determined to be health professional shortage areas under subparagraph (A) of the preceding sentence until the Secretary has afforded interested persons and groups in such area an opportunity to provide data and information in support of the designation as a health professional shortage area or a population group described in subparagraph (B) of such sentence or a facility described in subparagraph (C) of such sentence, and has made a determination on the basis of the data and information submitted by such persons and groups and other data and information available to the Secretary.

(2) For purposes of this subsection, the term "medical facility" means a facility for the delivery of health services and includes—

(A) a hospital, State mental hospital, public health center, outpatient medical facility, rehabilitation facility, facility for long-term care, community mental health center, migrant health center, facility operated by a city or county health department, and community health center and which is not reasonably accessible to an adequately served area;

(B) such a facility of a State correctional institution or of the Indian Health Service, and a health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act;

(C) such a facility used in connection with the delivery of health services under section 321 (relating to hospitals), 322 (relating to care and treatment of persons under quarantine and others), 323 (relating to care and treatment of Federal prisoners), 324 (relating to examination and treatment of certain Federal employees), 325 (relating to examination of aliens), 326 (relating to services to certain Federal employees), 320 (relating to services for persons with Hansen's disease), or 340 (relating to the provision of health services to homeless individuals); and

(D) a Federal medical facility.

(3) Homeless individuals (as defined in section 340(r)) may be a population group under paragraph (1).

(b) The Secretary shall establish by regulation criteria for the designation of areas, population groups, medical facilities, and other public facilities, in the States, as health professional shortage areas. In establishing such criteria, the Secretary shall take into consideration the following:

(1) The ratio of available health manpower to the number of individuals in an area or population group, or served by a

medical facility or other public facility under consideration for designation.

(2) Indicators of a need, notwithstanding the supply of health manpower, for health services for the individuals in an area or population group or served by a medical facility or other public facility under consideration for designation, with special consideration to indicators of—

- (A) infant mortality,
- (B) access to health services,
- (C) health status, and
- (D) ability to pay for health services.

(3) The percentage of physicians serving an area, population group, medical facility, or other public facility under consideration for designation who are employed by hospitals and who are graduates of foreign medical schools.

(c) In determining whether to make a designation, the Secretary shall take into consideration the following:

(1) The recommendations of the Governor of each State in which the area, population group, medical facility, or other public facility under consideration for designation is in whole or part located.

(2) The extent to which individuals who are (A) residents of the area, members of the population group, or patients in the medical facility or other public facility under consideration for designation, and (B) entitled to have payment made for medical services under title XVIII or XIX of the Social Security Act, cannot obtain such services because of suspension of physicians from the programs under such titles.

(d)(1) In accordance with the criteria established under subsection (b) and the considerations listed in subsection (c), the Secretary shall designate health professional shortage areas in the States, publish a descriptive list of the areas, population groups, medical facilities, and other public facilities so designated, and at least annually review and, as necessary, revise such designations.

(2) For purposes of paragraph (1), a complete descriptive list shall be published in the Federal Register not later than July 1 of 1991 and each subsequent year.

(e)(1) Prior to the designation of a public facility, including a Federal medical facility, as a health professional shortage area, the Secretary shall give written notice of such proposed designation to the chief administrative officer of such facility and request comments within 30 days with respect to such designation.

(2) Prior to the designation of a health professional shortage area under this section, the Secretary shall, to the extent practicable, give written notice of the proposed designation of such area to appropriate public or private nonprofit entities which are located or have a demonstrated interest in such area and request comments from such entities with respect to the proposed designation of such area.

(f) The Secretary shall give written notice of the designation of a health professional shortage area, not later than 60 days from the date of such designation, to—

(1) the Governor of each State in which the area, population group, medical facility, or other public facility so designated is in whole or part located; and

(2) appropriate public or nonprofit private entities which are located or which have a demonstrated interest in the area so designated.

(g) Any person may recommend to the Secretary the designation of an area, population group, medical facility, or other public facility as a health professional shortage area.

(h) The Secretary may conduct such information programs in areas, among population groups, and in medical facilities and other public facilities designated under this section as health professional shortage areas as may be necessary to inform public and nonprofit private entities which are located or have a demonstrated interest in such areas of the assistance available under this title by virtue of the designation of such areas.

ASSIGNMENT OF CORPS PERSONNEL

SEC. 333. [254f] (a)(1) The Secretary may assign members of the Corps to provide, under regulations promulgated by the Secretary, health services in or to a health professional shortage area during the assignment period (specified in the agreement described in section 334) only if—

(A) a public or nonprofit private entity, which is located or has a demonstrated interest in such area, makes application to the Secretary for such assignment;

(B) such application has been approved by the Secretary;

(C) an agreement has been entered into between the entity which has applied and the Secretary, in accordance with section 334; and

(D) the Secretary has (i) conducted an evaluation of the need and demand for health professional shortage area, the intended use of Corps members to be assigned to the area, community support for the assignment of Corps members to the area, the area's efforts to secure health professional shortage area, and the fiscal management capability of the entity to which Corps members would be assigned and (ii) on the basis of such evaluation has determined that—

(I) there is a need and demand for health manpower for the area;

(II) there has been appropriate and efficient use of any Corps members previously assigned to the entity for the area;

(III) there is general community support for the assignment of Corps members to the entity;

(IV) the area has made unsuccessful efforts to secure health manpower for the area; and

(V) there is a reasonable prospect of sound fiscal management, including efficient collection of fee-for-service, third-party, and other appropriate funds, by the entity with respect to Corps members assigned to such entity.

An application for assignment of a Corps member to a health professional shortage area shall include a demonstration by the appli-

cant that the area or population group to be served by the applicant has a shortage of personal health services and that the Corps member will be located so that the member will provide services to the greatest number of persons residing in such area or included in such population group. Such a demonstration shall be made on the basis of the criteria prescribed by the Secretary under section 332(b) and on additional criteria which the Secretary shall prescribe to determine if the area or population group to be served by the applicant has a shortage of personal health services.

(2) Corps members may be assigned to a Federal health care facility, but only upon the request of the head of the department or agency of which such facility is a part.

(3) In approving applications for assignment of members of the Corps the Secretary shall not discriminate against applications from entities which are not receiving Federal financial assistance under this Act.

(b)(1) The Secretary may not approve an application for the assignment of a member of the Corps described in subparagraph (C) of section 331(a)(1) to an entity unless the application of the entity contains assurances satisfactory to the Secretary that the entity (A) has sufficient financial resources to provide the member of the Corps with an income of not less than the income to which the member would be entitled if the member was a member described in subparagraph (B) of section 331(a)(1), or (B) would have such financial resources if a grant was made to the entity under paragraph (2).

(2)(A) If in approving an application of an entity for the assignment of a member of the Corps described in subparagraph (C) of section 331(a)(1) the Secretary determines that the entity does not have sufficient financial resources to provide the member of the Corps with an income of not less than the income to which the member would be entitled if the member was a member described in subparagraph (B) of section 331(a)(1), the Secretary may make a grant to the entity to assure that the member of the Corps assigned to it will receive during the period of assignment to the entity such an income.

(B) The amount of any grant under subparagraph (A) shall be determined by the Secretary. Payments under such a grant may be made in advance or by way of reimbursement, and at such intervals and on such conditions, as the Secretary finds necessary. No grant may be made unless an application therefor is submitted to and approved by the Secretary. Such an application shall be in such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe.

(c) The Secretary shall assign Corps members to entities in health professional shortage areas without regard to the ability of the individuals in such areas, population groups, medical facilities, or other public facilities to pay for such services.

(d)(1) The Secretary may provide technical assistance to a public or nonprofit private entity which is located in a health professional shortage area and which desires to make an application under this section for assignment of a Corps member to such area. Assistance provided under this paragraph may include assistance to an entity in (A) analyzing the potential use of health professions

personnel in defined health services delivery areas by the residents of such areas, (B) determining the need for such personnel in such areas, (C) determining the extent to which such areas will have a financial base to support the practice of such personnel and the extent to which additional financial resources are needed to adequately support the practice, and (D) determining the types of inpatient and other health services that should be provided by such personnel in such areas.

(2) The Secretary may provide, to public and nonprofit private entities which are located in a health professional shortage area to which area a Corps member has been assigned, technical assistance to assist in the retention of such member in such area after the completion of such member's assignment to the area.

(3) The Secretary may provide, to health professional shortage areas to which no Corps member has been assigned, (A) technical assistance to assist in the recruitment of health manpower for such areas, and (B) current information on public and private programs which provide assistance in the securing of health manpower.

(4)(A) The Secretary shall undertake to demonstrate the improvements that can be made in the assignment of members of the Corps to health professional shortage areas and in the delivery of health care by Corps members in such areas through coordination with States, political subdivisions of States, agencies of States and political subdivisions, and other public and nonprofit private entities which have expertise in the planning, development, and operation of centers for the delivery of primary health care. In carrying out this subparagraph, the Secretary shall enter into agreements with qualified entities which provide that if—

(i) the entity places in effect a program for the planning, development, and operation of centers for the delivery of primary health care in health professional shortage areas which reasonably addresses the need for such care in such areas, and

(ii) under the program the entity will perform the functions described in subparagraph (B),

the Secretary will assign under this section members of the Corps in accordance with the program.

(B) For purposes of subparagraph (A), the term "qualified entity" means a State, political subdivision of a State, an agency of a State or political subdivision, or other public or nonprofit private entity operating solely within one State, which the Secretary determines is able—

(i) to analyze the potential use of health professions personnel in defined health services delivery areas by the residents of such areas;

(ii) to determine the need for such personnel in such areas and to recruit, select, and retain health professions personnel (including members of the National Health Service Corps) to meet such need;

(iii) to determine the extent to which such areas will have a financial base to support the practice of such personnel and the extent to which additional financial resources are needed to adequately support the practice;

(iv) to determine the types of inpatient and other health services that should be provided by such personnel in such areas;

(v) to assist such personnel in the development of their clinical practice and fee schedules and in the management of their practice;

(vi) to assist in the planning and development of facilities for the delivery of primary health care; and

(vii) to assist in establishing the governing bodies of centers for the delivery of such care and to assist such bodies in defining and carrying out their responsibilities.

(e) Notwithstanding any other law, any member of the Corps licensed to practice medicine, osteopathic medicine, dentistry, or any other health profession in any State shall, while serving in the Corps, be allowed to practice such profession in any State.

SEC. 333A. [254f-1] PRIORITIES IN ASSIGNMENT OF CORPS PERSONNEL.

(a) IN GENERAL.—In approving applications made under section 333 for the assignment of Corps members, the Secretary shall—

(1) give priority to any such application that—

(A) is made regarding the provision of primary health services to a health professional shortage area with the greatest such shortage, as determined in accordance with subsection (b); and

(B) is made by an entity that—

(i) serves a health professional shortage area described in subparagraph (A);

(ii) coordinates the delivery of primary health services with related health and social services;

(iii) has a documented record of sound fiscal management; and

(iv) will experience a negative impact on its capacity to provide primary health services if a Corps member is not assigned to the entity;

(2) with respect to the geographic area in which the health professional shortage area is located, take into consideration the willingness of individuals in the geographic area, and of the appropriate governmental agencies or health entities in the area, to assist and cooperate with the Corps in providing effective primary health services; and

(3) take into consideration comments of medical, osteopathic, dental, or other health professional societies whose members deliver services to the health professional shortage area, or if no such societies exist, comments of physicians, dentists, or other health professionals delivering services to the area.

(b) EXCLUSIVE FACTORS FOR DETERMINING GREATEST SHORTAGES.—In making a determination under subsection (a)(1)(A) of the health professional shortage areas with the greatest such shortages, the Secretary may consider only the following factors:

(1) The ratio of available health manpower to the number of individuals in the area or population group involved, or served by the medical facility or other public facility involved.

(2) Indicators of need as follows:

(A) The rate of low birthweight births.

(B) The rate of infant mortality.

(C) The rate of poverty.

(D) Access to primary health services, taking into account the distance to such services.

(c) ESTABLISHMENT OF CRITERIA FOR DETERMINING PRIORITIES.—

(1) IN GENERAL.—The Secretary shall establish criteria specifying the manner in which the Secretary makes a determination under subsection (a)(1)(A) of the health professional shortage areas with the greatest such shortages. Such criteria shall specify the manner in which the factors described in subsection (b) are implemented regarding such a determination.

(2) PUBLICATION OF CRITERIA.—The criteria required in paragraph (1) shall be published in the Federal Register not later than July 1, 1991. Any revisions made in the criteria by the Secretary shall be effective upon publication in the Federal Register.

(d) NOTIFICATIONS REGARDING PRIORITIES.—

(1) PREPARATION OF LIST FOR APPLICABLE PERIOD.—For the purpose of carrying out paragraph (2), the Secretary shall prepare a list of health professional shortage areas that are receiving priority under subsection (a)(1) in the assignment of Corps members for the period applicable under subsection (f). Such list—

(A) shall include a specification, for each such health professional shortage area, of the entities for which the Secretary has provided an authorization to receive assignments of Corps members in the event that Corps members are available for the assignments; and

(B) shall, of the entities for which an authorization described in subparagraph (A) has been provided, specify—

(i) the entities provided such an authorization for the assignment of Corps members who are participating in the Scholarship Program;

(ii) the entities provided such an authorization for the assignment of Corps members who are participating in the Loan Repayment Program; and

(iii) the entities provided such an authorization for the assignment of Corps members who have become Corps members other than pursuant to contractual obligations under the Scholarship or Loan Repayment Programs.

The Secretary may set forth such specifications by medical specialty.

(2) NOTIFICATION OF AFFECTED PARTIES.—

(A) Not later than 30 days after the preparation of each list under paragraph (1), the Secretary shall notify entities specified for purposes of subparagraph (A) of such paragraph of the fact that the entities have been provided an authorization to receive assignments of Corps members in the event that Corps members are available for the assignments.

(B) In the case of individuals with respect to whom a period of obligated service under the Scholarship Program will begin during the period under subsection (f) for which a list under paragraph (1) is prepared, the Secretary shall, not later than 30 days after the preparation of each such list, provide to such individuals the names of each of the entities specified for purposes of paragraph (1)(B)(i) that is appropriate to the medical specialty of the individuals.

(3) REVISIONS IN LIST.—If the Secretary makes a revision in a list under paragraph (1) during the period under subsection (f) to which the list is applicable, and the revision alters the status of an entity with respect to the list, the Secretary shall notify the entity of the effect on the entity of the revision. Such notification shall be provided not later than 30 days after the date on which the revision is made.

(e) LIMITATION ON NUMBER OF ENTITIES OFFERED AS ASSIGNMENT CHOICES IN SCHOLARSHIP PROGRAM.—

(1) DETERMINATION OF AVAILABLE CORPS MEMBERS.—The Secretary shall determine the number of participants in the Scholarship Program who are available for assignments under section 333 for the period applicable under subsection (f).

(2) AVAILABILITY OF 500 OR FEWER MEMBERS.—If the number of participants for purposes of paragraph (1) is less than 500, the Secretary shall limit the number of entities specified under subsection (d)(1)(B)(i) to the lesser of—

(A) 500 such entities; and

(B) a number of such entities constituting 300 percent of the number of such participants available for assignment under section 333.

(3) AVAILABILITY OF MORE THAN 500 MEMBERS.—If the number of participants for purposes of paragraph (1) is equal to or greater than 500, the Secretary shall determine the number of entities to be specified under subsection (d)(1)(B)(i), subject to ensuring that assignments of such participants are made to 500 entities that serve health professional shortage areas that have chronic difficulty in recruiting and retaining health professionals to provide primary health services.

(4) ADJUSTMENT IN BASE NUMBER.—The number 500, as used for purposes of paragraphs (2) and (3), may by regulation be adjusted by the Secretary to a greater or a lesser number.

(f) APPLICABLE PERIOD REGARDING PRIORITIES.—

(1) IN GENERAL.—With respect to determinations under subsection (a)(1) of the applications that are to be given priority regarding the assignment of Corps members, the Secretary shall make such a determination not less than once each fiscal year. The first determination shall be made not later than July 1 of the year preceding the year in which the period of obligated service begins. If the Secretary revises the determination before July 1 of the following year, the revised determination shall be applicable with respect to assignments of Corps members made during the period beginning on the date of the issuance of the revised determination and ending on July 1 of such year.

(2) DATE CERTAIN FOR PREPARATION OF NOTIFICATION LIST.—A list under subsection (d)(1) shall be prepared for each of the periods described in paragraph (1). Each such list shall be prepared not later than the date on which a determination of priorities under such paragraph is required to be made for the period involved.

COST SHARING

SEC. 334. [254g] (a) The Secretary shall require, as a condition to the approval of an application under section 333 for the assignment of a member of the Corps, that the entity which submitted the application enter into an agreement for a specific assignment period (not to exceed 4 years) with the Secretary under which—

(1) the entity shall be responsible for charging, in accordance with subsection (d), for health services provided by Corps members assigned to the entity;

(2) the entity shall take such action as may be reasonable for the collection of payments for such health services, including, if a Federal agency, an agency of a State or local government, or other third party would be responsible for all or part of the cost of such health services if it had not been provided by Corps members under this subpart, the collection, on a fee-for-service or other basis, from such agency or third party, the portion of such cost for which it would be so responsible (and in determining the amount of such cost which such agency or third party would be responsible, the health services provided by Corps members shall be considered as being provided by private practitioners);

(3) the entity, if not a small health center, shall pay to the United States, as prescribed by the Secretary in each calendar quarter (or other period as may be specified in the agreement) during which any Corps member is assigned to such entity, the sum of—

(A) an amount calculated by the Secretary to reflect the average salary (including amounts paid in accordance with section 331(d)) and allowances of comparable Corps members for a calendar quarter (or other period);

(B) that portion of an amount calculated by the Secretary to reflect the average amount paid under the Scholarship Program or the Loan Repayment Program to or on behalf of comparable Corps members that bears the same ratio to the calculated amount as the number of days of service provided by the member during that quarter (or other period) bears to the number of days in his period of obligated service under the Scholarship Program or the Loan Repayment Program; and

(C) if such entity received a loan under section 335(c) or a grant under section 333(d)(2),¹ an amount which bears the same ratio to the amount of such loan or grant as the number of days in such quarter (or other period) during which any Corps members were assigned to the en-

¹ So in original. Probably should be "section 333(b)(2)". See the redesignations made by section 103(b)(2) of Public Law 101-597 (104 Stat. 3015).

tity bears to the number of days in the assignment period after such entity received such loan or grant;

(4) the entity, if a small health center, shall pay to the United States, in each calendar quarter (or other period as may be specified in the agreement) during which any Corps member is assigned to such entity, an amount determined by the Secretary in accordance with subsection (f); and

(5) the entity shall prepare and submit to the Secretary an annual report, in such form and manner, as the Secretary may require.

(b)(1) The Secretary may waive in whole or in part, on a prospective or retrospective basis, the application of the requirement of subsection (a)(3) for an entity which is not a small health center if he determines that the entity is financially unable to meet such requirement or if he determines that compliance with such requirement would unreasonably limit the ability of the entity to provide for the adequate support of the provision of health services by Corps members.

(2) The Secretary may waive in whole or in part, on a prospective or retrospective basis, the application of the requirement of subsection (a)(3) for any entity which is not a small health center and which is located in a health professional shortage area in which a significant percentage of the individuals are elderly, living in poverty, or have other characteristics which indicate an inability to repay, in whole or in part, the amounts required in subsection (a)(3).

(3) In the event that the Secretary grants a waiver under paragraph (1) or (2), and does not, pursuant to paragraph (5), require payment by the entity in the amount described in subsection (f)(1), the entity shall be required to use the total amount of funds collected by such entity in accordance with subsection (a)(2) for the improvement of the capability of such entity to deliver health services to the individuals in, or served by, the health professional shortage area.

(4) In determining whether to grant a waiver under paragraph (1) or (2), the Secretary shall not discriminate against a public entity.

(5)(A) If the Secretary determines that an entity which is not a small health center is eligible for a waiver under paragraph (1) or (2), the Secretary may waive the application of subsection (a)(3) for such entity and require such entity to make payment in an amount equal to the amount described in subsection (f)(1) that would be payable by such entity if such entity were a small health center.

(B) The Secretary may waive in whole or in part, on a prospective or retrospective basis, the application of the requirement of subparagraph (A) for any entity if the Secretary determines that the entity is financially unable to meet such requirement or that compliance with such requirement would unreasonably limit the ability of the entity to provide for the adequate support of the provision of health services by Corps members. Funds which would be paid to the United States but for a waiver under this subparagraph shall be used by an entity to—

(i) expand or improve its provision of health services;

- (ii) increase the number of individuals served;
- (iii) renovate or modernize facilities for its provision of health services;
- (iv) improve the administration of its health service programs; or
- (v) to establish a financial reserve to assure its ability to continue providing health services.

(c) The excess (if any) of the amount of funds collected by an entity which is not a small health center in accordance with subsection (a)(2) over the amount paid to the United States in accordance with subsection (a)(3) or subsection (b)(5)(A) shall be used by the entity to expand and improve the provision of health services to the individuals in the health professional shortage area for which the entity submitted an application or to recruit and retain health manpower to provide health services for such individuals.

(d) Any person who receives health services provided by a Corps member under this subpart shall be charged for such services on a fee-for-service or other basis, at a rate approved by the Secretary, pursuant to regulations. Such rate shall be computed in such a way as to permit the recovery of the value of such services, except that if such person is determined under regulations of the Secretary to be unable to pay such charge, the Secretary shall provide for the furnishing of such services at a reduced rate or without charge.

(e) Funds received by the Secretary under an agreement entered into under this section shall be deposited in the Treasury as miscellaneous receipts and shall be disregarded in determining the amounts of appropriations to be requested and the amounts to be made available from appropriations made under section 338 to carry out sections 331 through 335 and section 337.

(f)(1) An entity which is a small health center shall pay to the United States, as prescribed by the Secretary in each calendar quarter (or other period as may be specified in the agreement) during which any Corps member is assigned to such entity, an amount equal to the amount (prorated for a calendar quarter or other period) by which the revenues that the center may reasonably expect to receive during an annual period for the provision of health services exceeds the costs that the center may reasonably expect to incur in the provision of such services, except that the amount that an entity shall pay to the United States under this paragraph shall not exceed the amount such entity would pay to the United States under paragraph (3) of subsection (a) if such paragraph applied to such entity.

(2)(A) To determine for purposes of paragraph (1) the revenues and costs which an entity that is a small health center may reasonably be expected to receive and incur in an annual period for the provision of health services, the entity shall submit to the Secretary before the beginning of such period a proposed budget which—

- (i) describes the primary and supplemental health services (as defined in section 330) which are needed by the area the entity serves in such period; and

(ii) states the revenues and costs which the entity expects to receive and incur in providing such health services in such period.

(B) From the submission under subparagraph (A) and other information available to the Secretary, the Secretary shall determine—

(i) the primary and supplemental health services (as defined in section 330) needed in the area the entity serves;

(ii) the fees, premiums, third party reimbursements, and other revenues the entity making the submission may reasonably expect to receive from the provision of such services; and

(iii) the costs which the entity may reasonably expect to incur in providing such services.

The revenues and costs determined by the Secretary shall be the revenues and costs used in making the determination under paragraph (1).

(C)(i) A determination under subparagraph (B) regarding the revenues and costs of an entity in an annual period shall be made by the Secretary utilizing criteria specific to the entity and shall be made without regard to whether the entity is making progress toward collecting sufficient revenues to provide an adequate level of primary health services without the assignment of Corps members.

(ii) In making a determination referred to in clause (i)—

(I) the Secretary may consider whether the proposed budget submitted under subparagraph (A) provides a reasonable estimate regarding the revenues and costs of the entity; and

(II) may not consider the reasonableness of the amount of revenues collected, or the amount of costs incurred by the entity, except to the extent necessary to ensure that the entity is operating in good faith and is operating efficiently with respect to fiscal matters within the control of the entity.

(iii) A determination of whether an entity is eligible for a waiver under paragraph (3) shall be made by the Secretary without regard to the revenues and costs determined by the Secretary under subparagraph (B).

(iv) A determination of whether an entity is a small health center shall be made by the Secretary without regard to the revenues and costs determined by the Secretary under subparagraph (B).

(3) The Secretary may waive in whole or in part, on a prospective or retrospective basis, the application of paragraph (1) for an entity which is a small health center if the Secretary determines that the entity needs all or part of the amounts otherwise payable under such paragraph to—

(A) expand or improve its provision of health services;

(B) increase the number of individuals served;

(C) renovate or modernize facilities for its provision of health services;

(D) improve the administration of its health service programs; or

(E) establish a financial reserve to assure its ability to continue providing health services.

(4) The excess (if any) of the amount of funds collected by an entity which is a small health center in accordance with subsection (a)(2) over the amount paid to the United States in accordance with

paragraph (1) of this subsection shall be used by the center for the purposes set out in subparagraphs (A) through (E) of paragraph (3) of this subsection or to recruit and retain health manpower to provide health services to the individuals in the health professional shortage area for which the entity submitted an application.

(5) For purposes of this section, the term "small health center" means an entity other than—

(A) a hospital (or part of a hospital);

(B) a public entity; or

(C) an entity that is receiving a grant under section 329 or section 330, except that such term includes an entity whose grant is less than the total of the amounts, calculated on an annual basis, specified in subparagraphs (A) and (B) of subsection (a)(3).

PROVISION OF HEALTH SERVICES BY CORPS MEMBERS

SEC. 335. [254h] (a) In providing health services in a health professional shortage area, Corps members shall utilize the techniques, facilities, and organizational forms most appropriate for the area, population group, medical facility, or other public facility, and shall, to the maximum extent feasible, provide such services (1) to all individuals in, or served by, such health professional shortage area regardless of their ability to pay for the services, and (2) in a manner which is cooperative with other health care providers serving such health professional shortage area.

(b)(1) Notwithstanding any other provision of law, the Secretary may (A) to the maximum extent feasible make such arrangements as he determines necessary to enable Corps members to utilize the health facilities in or serving the health professional shortage area in providing health services; (B) make such arrangements as he determines are necessary for the use of equipment and supplies of the Service and for the lease or acquisition of other equipment and supplies; and (C) secure the permanent or temporary services of physicians, dentists, nurses, administrators, and other health personnel. If there are no health facilities in or serving such area, the Secretary may arrange to have Corps members provide health services in the nearest health facilities of the Service or may lease or otherwise provide facilities in or serving such area for the provision of health services.

(2) If the individuals in or served by a health professional shortage area are being served (as determined under regulations of the Secretary) by a hospital or other health care delivery facility of the Service, the Secretary may, in addition to such other arrangements as he may make under paragraph (1), arrange for the utilization of such hospital or facility by Corps members in providing health services, but only to the extent that such utilization will not impair the delivery of health services and treatment through such hospital or facility to individuals who are entitled to health services and treatment through such hospital or facility.

(c) The Secretary may make one loan to any entity with an approved application under section 333 to assist such entity in meeting the costs of (1) establishing medical, dental, or other health profession practices, including the development of medical practice management systems; (2) acquiring equipment for use in providing

health services; and (3) renovating buildings to establish health facilities. No loan may be made under this subsection unless an application therefor is submitted to, and approved by, the Secretary. The amount of any such loan shall be determined by the Secretary, except that no such loan may exceed \$50,000.

(d) Upon the expiration of the assignment of all Corps members to a health professional shortage area, the Secretary may (notwithstanding any other provision of law) sell, to any appropriate local entity, equipment and other property of the United States utilized by such members in providing health services. Sales made under this subsection shall be made at the fair market value (as determined by the Secretary) of the equipment or such other property; except that the Secretary may make such sales for a lesser value to an appropriate local entity, if he determines that the entity is financially unable to pay the full market value.

(e)(1)(A) It shall be unlawful for any hospital to deny an authorized Corps member admitting privileges when such Corps member otherwise meets the professional qualifications established by the hospital for granting such privileges and agrees to abide by the published bylaws of the hospital and the published bylaws, rules, and regulations of its medical staff.

(B) Any hospital which is found by the Secretary, after notice and an opportunity for a hearing on the record, to have violated this subsection shall upon such finding cease, for a period to be determined by the Secretary, to receive and to be eligible to receive any Federal funds under this Act or under titles XVIII or XIX of the Social Security Act.

(2) For purposes of this subsection, the term "hospital" includes a State or local public hospital, a private profit hospital, a private nonprofit hospital, a general or special hospital, and any other type of hospital (excluding a hospital owned or operated by an agency of the Federal Government), and any related facilities.

SEC. 336. [254h-1] FACILITATION OF EFFECTIVE PROVISION OF CORPS SERVICES.

(a) CONSIDERATION OF INDIVIDUAL CHARACTERISTICS OF MEMBERS IN MAKING ASSIGNMENTS.—In making an assignment of a Corps member to an entity that has had an application approved under section 333, the Secretary shall, subject to making the assignment in accordance with section 333A, seek to assign to the entity a Corps member who has (and whose spouse, if any, has) characteristics that increase the probability that the member will remain in the health professional shortage area involved after the completion of the period of service in the Corps.

(b) COUNSELING ON SERVICE IN CORPS.—

(1) IN GENERAL.—The Secretary shall, subject to paragraph (3), offer appropriate counseling on service in the Corps to individuals during the period of membership in the Corps, particularly during the initial period of each assignment.

(2) CAREER ADVISOR REGARDING OBLIGATED SERVICE.—

(A) In the case of individuals who have entered into contracts for obligated service under the Scholarship or Loan Repayment Program, counseling under paragraph (1) shall include appropriate counseling on matters particular to such obligated service. The Secretary shall ensure that

career advisors for providing such counseling are available to such individuals throughout the period of participation in the Scholarship or Loan Repayment Program.

(B) With respect to the Scholarship Program, counseling under paragraph (1) shall include counseling individuals during the period in which the individuals are pursuing an educational degree in the health profession involved, including counseling to prepare the individual for service in the Corps.

(3) EXTENT OF COUNSELING SERVICES.—With respect to individuals who have entered into contracts for obligated service under the Scholarship or Loan Repayment Program, this subsection shall be carried out regarding such individuals throughout the period of obligated service (and, additionally, throughout the period specified in paragraph (2)(B), in the case of the Scholarship Program). With respect to Corps members generally, this subsection shall be carried out to the extent practicable.

(c) GRANTS REGARDING PREPARATION OF STUDENTS FOR PRACTICE.—With respect to individuals who have entered into contracts for obligated service under the Scholarship or Loan Repayment Program, the Secretary may make grants to, and enter into contracts with, public and nonprofit private entities (including health professions schools) for the conduct of programs designed to prepare such individuals for the effective provision of primary health services in the health manpower shortage areas¹ to which the individuals are assigned.

(d) ASSISTANCE IN ESTABLISHING LOCAL PROFESSIONAL RELATIONSHIPS.—The Secretary shall assist Corps members in establishing appropriate professional relationships between the Corps member involved and the health professions community of the geographic area with respect to which the member is assigned, including such relationships with hospitals, with health professions schools, with area health education centers under section 781, with health education and training centers under such section, and with border health education and training centers under such section. Such assistance shall include assistance in obtaining faculty appointments at health professions schools.

(e) TEMPORARY RELIEF FROM CORPS DUTIES.—

(1) IN GENERAL.—The Secretary shall, subject to paragraph (4), provide assistance to Corps members in establishing arrangements through which Corps members may, as appropriate, be provided temporary relief from duties in the Corps in order to pursue continuing education in the health professions, to participate in exchange programs with teaching centers, to attend professional conferences, or to pursue other interests, including vacations.

(2) ASSUMPTION OF DUTIES OF MEMBER.—

(A) Temporary relief under paragraph (1) may be provided only if the duties of the Corps member involved are assumed by another health professional. With respect to such temporary relief, the duties may be assumed by

¹ So in original. Probably should be "health professional shortage areas".

Corps members or by health professionals who are not Corps members, if the Secretary approves the professionals for such purpose. Any health professional so approved by the Secretary shall, during the period of providing such temporary relief, be deemed to be a Corps member for purposes of section 224 (including for purposes of the remedy described in such section), section 333(f)¹, and section 335(e).

(B) In carrying out paragraph (1), the Secretary shall provide for the formation and continued existence of a group of health professionals to provide temporary relief under such paragraph.

(3) RECRUITMENT FROM GENERAL HEALTH PROFESSIONS COMMUNITY.—In carrying out paragraph (1), the Secretary shall—

(A) encourage health professionals who are not Corps members to enter into arrangements under which the health professionals temporarily assume the duties of Corps members for purposes of paragraph (1); and

(B) with respect to the entities to which Corps members have been assigned under section 333, encourage the entities to facilitate the development of arrangements described in subparagraph (A).

(4) LIMITATION.—In carrying out paragraph (1), the Secretary may not, except as provided in paragraph (5), obligate any amounts (other than for incidental expenses) for the purpose of—

(A) compensating a health professional who is not a Corps member for assuming the duties of a Corps member; or

(B) paying the costs of a vacation, or other interests that a Corps member may pursue during the period of temporary relief under such paragraph.

(5) SOLE PROVIDERS OF HEALTH SERVICES.—In the case of any Corps member who is the sole provider of health services in the geographic area involved, the Secretary may, from amounts appropriated under section 338, obligate on behalf of the member such sums as the Secretary determines to be necessary for purposes of providing temporary relief under paragraph (1).

(f) DETERMINATIONS REGARDING EFFECTIVE SERVICE.—In carrying out subsection (a) and sections 338A(d) and 338B(d), the Secretary shall carry out activities to determine—

(1) the characteristics of physicians, dentists, and other health professionals who are more likely to remain in practice in health manpower shortage areas² after the completion of the period of service in the Corps;

(2) the characteristics of health manpower shortage areas, and of entities seeking assignments of Corps members, that

¹So in original. As a result of the amendments made by section 103(b) of Public Law 101-597, there is no subsection (f) in section 333. (Subsection (e) of section 333, like sections 224 and 335(e), establishes a right for Corps members.)

²So in original. Probably should be "health professional shortage areas".

are more likely to retain Corps members after the members have completed the period of service in the Corps; and

(3) the appropriate conditions for the assignment and utilization in health manpower shortage areas² of certified nurse practitioners, certified nurse midwives, and physician assistants.

ANNUAL REPORTS

SEC. 336A. [254i] The Secretary shall submit an annual report to Congress, and shall include in such report with respect to the previous calendar year—

(1) the number, identity, and priority of all health professional shortage areas designated in such year and the number of health professional shortage areas which the Secretary estimates will be designated in the subsequent year;

(2) the number of applications filed under section 333 in such year for assignment of Corps members and the action taken on each such application;

(3) the number and types of Corps members assigned in such year to health professional shortage areas, the number and types of additional Corps members which the Secretary estimates will be assigned to such areas in the subsequent year, and the need for additional members for the Corps;

(4) the recruitment efforts engaged in for the Corps in such year and the number of qualified individuals who applied for service in the Corps in such year;

(5) the number of patients seen and the number of patient visits recorded during such year with respect to each health professional shortage area to which a Corps member was assigned during such year;

(6) the number of Corps members who elected, and the number of Corps members who did not elect, to continue to provide health services in health professional shortage areas after termination of their service in the Corps and the reasons (as reported to the Secretary) of members who did not elect for not making such election;

(7) the results of evaluations and determinations made under section 333(a)(1)(D) during such year; and

(8) the amount charged during such year for health services provided by Corps members, the amount which was collected in such year by entities in accordance with agreements under section 334, and the amount which was paid to the Secretary in such year under such agreements.

NATIONAL ADVISORY COUNCIL

SEC. 337. [254j] (a) There is established a council to be known as the National Advisory Council on the National Health Service Corps (hereinafter in this section referred to as the "Council"). The Council shall be composed of fifteen members appointed by the Secretary. The Council shall consult with, advise, and make recommendations to, the Secretary with respect to his responsibilities in carrying out this subpart (other than section 338G), and shall

review and comment upon regulations promulgated by the Secretary under this subpart.

(b)(1) Members of the Council shall be appointed for a term of three years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term. No member shall be removed, except for cause. Members may not be reappointed to the Council.

(2) Members of the Council (other than members who are officers or employees of the United States), while attending meetings or conferences thereof or otherwise serving on the business of the Council, shall be entitled to receive for each day (including travel-time) in which they are so serving compensation at a rate fixed by the Secretary (but not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule); and while so serving away from their homes or regular places of business all members may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently.

(c) Section 14 of the Federal Advisory Committee Act shall not apply with respect to the Council.

AUTHORIZATION OF APPROPRIATION

SEC. 338. [254k] (a)(1) For the purpose of carrying out this subpart, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 2000.

(2) In the case of individuals who serve in the Corps other than pursuant to obligated service under the Scholarship or Loan Repayment Program, the Secretary each fiscal year shall, to the extent practicable, make assignments under section 333 of such individuals who are certified nurse midwives, certified nurse practitioners, or physician assistants.

(b) An appropriation under an authorization under subsection (a) for any fiscal year may be made at any time before that fiscal year and may be included in an Act making an appropriation under an authorization under subsection (a) for another fiscal year; but no funds may be made available from any appropriation under such authorization for obligation under sections 331 through 335, section 336A, and section 337 before the fiscal year for which such appropriation is authorized.

Subpart III—Scholarship Program and Loan Repayment Program

NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP PROGRAM

SEC. 338A. [254l] (a) The Secretary shall establish the National Health Service Corps Scholarship Program to assure, with respect to the provision of primary health services pursuant to section 331(a)(2)—

(1) an adequate supply of physicians, dentists, certified nurse midwives, certified nurse practitioners, and physician assistants; and

(2) if needed by the Corps, an adequate supply of other health professionals.

(b) To be eligible to participate in the Scholarship Program, an individual must—

(1) be accepted for enrollment, or be enrolled, as a full-time student (A) in an accredited (as determined by the Secretary) educational institution in a State and (B) in a course of study or program, offered by such institution and approved by the Secretary, leading to a degree in medicine, osteopathic medicine, dentistry, or other health profession;

(2) be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the Corps;

(3) submit an application to participate in the Scholarship Program; and

(4) sign and submit to the Secretary, at the time of submission of such application, a written contract (described in subsection (f)) to accept payment of a scholarship and to serve (in accordance with this subpart) for the applicable period of obligated service in a health professional shortage area.

(c)(1) In disseminating application forms and contract forms to individuals desiring to participate in the Scholarship Program, the Secretary shall include with such forms—

(A) a fair summary of the rights and liabilities of an individual whose application is approved (and whose contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled under section 338D¹ in the case of the individual's breach of the contract; and

(B) information respecting meeting a service obligation through private practice under an agreement under section 338C² and such other information as may be necessary for the individual to understand the individual's prospective participation in the Scholarship Program and service in the Corps, including a statement of all factors considered in approving applications for participation in the Program and in making assignments for participants in the Program.

(2) The application form, contract form, and all other information furnished by the Secretary under this subpart shall be written in a manner calculated to be understood by the average individual applying to participate in the Scholarship Program. The Secretary shall make such application forms, contract forms, and other information available to individuals desiring to participate in the Scholarship Program on a date sufficiently early to insure that such individuals have adequate time to carefully review and evaluate such forms and information.

(3)(A) The Secretary shall distribute to health professions schools materials providing information on the Scholarship Program and shall encourage the schools to disseminate the materials to the students of the schools.

¹ So in original. Probably should be "section 338E".

² So in original. Probably should be "section 338D".

(B)(i) In the case of any health professional whose period of obligated service under the Scholarship Program is nearing completion, the Secretary shall encourage the individual to remain in a health professional shortage area and to continue providing primary health services.

(ii) During the period in which a health professional is planning and making the transition to private practice from obligated service under the Scholarship Program, the Secretary may provide assistance to the professional regarding such transition if the professional is remaining in a health professional shortage area and is continuing to provide primary health services.

(C) In the case of entities to which participants in the Scholarship Program are assigned under section 333, the Secretary shall encourage the entities to provide options with respect to assisting the participants in remaining in the health professional shortage areas involved, and in continuing to provide primary health services, after the period of obligated service under the Scholarship Program is completed. The options with respect to which the Secretary provides such encouragement may include options regarding the sharing of a single employment position in the health professions by 2 or more health professionals, and options regarding the recruitment of couples where both of the individuals are health professionals.

(d)(1) Subject to section 333A, in providing contracts under the Scholarship Program—

(A) the Secretary shall consider the extent of the demonstrated interest of the applicants for the contracts in providing primary health services; and

(B) may consider such other factors regarding the applicants as the Secretary determines to be relevant to selecting qualified individuals to participate in such Program.

(2) In providing contracts under the Scholarship Program, the Secretary shall give priority—

(A) first, to any application for such a contract submitted by an individual who has previously received a scholarship under this section or under section 758;

(B) second, to any application for such a contract submitted by an individual who has characteristics that increase the probability that the individual will continue to serve in a health professional shortage area after the period of obligated service pursuant to subsection (f) is completed; and

(C) third, subject to subparagraph (B), to any application for such a contract submitted by an individual who is from a disadvantaged background.

(e)(1) An individual becomes a participant in the Scholarship Program only upon the Secretary's approval of the individual's application submitted under subsection (b)(3) and the Secretary's acceptance of the contract submitted by the individual under subsection (b)(4).

(2) The Secretary shall provide written notice to an individual promptly upon the Secretary's approving, under paragraph (1), of the individual's participation in the Scholarship Program.

(f) The written contract (referred to in this subpart) between the Secretary and an individual shall contain—

(1) an agreement that—

(A) subject to paragraph (2), the Secretary agrees (i) to provide the individual with a scholarship (described in subsection (g)) in each such school year or years for a period of years (not to exceed four school years) determined by the individual, during which period the individual is pursuing a course of study described in subsection (b)(1)(B), and (ii) to accept (subject to the availability of appropriated funds for carrying out sections 331 through 335 and section 337) the individual into the Corps (or for equivalent service as otherwise provided in this subpart); and

(B) subject to paragraph (2), the individual agrees—

(i) to accept provision of such a scholarship to the individual;

(ii) to maintain enrollment in a course of study described in subsection (b)(1)(B) until the individual completes the course of study;

(iii) while enrolled in such course of study, to maintain an acceptable level of academic standing (as determined under regulations of the Secretary by the educational institution offering such course of study); and

(iv) to serve for a time period (hereinafter in the subpart referred to as the "period of obligated service") equal to—

(I) one year for each school year for which the individual was provided a scholarship under the Scholarship Program, or

(II) two years,

whichever is greater, as a provider of primary health services in a health professional shortage area (designated under section 332) to which he is assigned by the Secretary as a member of the Corps, or as otherwise provided in this subpart;

(2) a provision that any financial obligation of the United States arising out of a contract entered into under this subpart and any obligation of the individual which is conditioned thereon, is contingent upon funds being appropriated for scholarships under this subpart and to carry out the purposes of sections 331 through 335 and sections 337 and 338;

(3) a statement of the damages to which the United States is entitled, under section 338D¹ for the individual's breach of the contract; and

(4) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with the provisions of this subpart.

(g)(1) A scholarship provided to a student for a school year under a written contract under the Scholarship Program shall consist of—

¹ So in original. Probably should be "section 338E".

(A) payment to, or (in accordance with paragraph (2)) on behalf of, the student of the amount (except as provided in section 711) of—

- (i) the tuition of the student in such school year; and
- (ii) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the student in such school year; and

(B) payment to the student of a stipend of \$400 per month (adjusted in accordance with paragraph (3)) for each of the 12 consecutive months beginning with the first month of such school year.

(2) The Secretary may contract with an educational institution, in which a participant in the Scholarship Program is enrolled, for the payment to the educational institution of the amounts of tuition and other reasonable educational expenses described in paragraph (1)(A). Payment to such an educational institution may be made without regard to section 3648 of the Revised Statutes (31 U.S.C. 529).

(3) The amount of the monthly stipend, specified in paragraph (1)(B) and as previously adjusted (if at all) in accordance with this paragraph, shall be increased by the Secretary for each school year ending in a fiscal year beginning after September 30, 1978, by an amount (rounded to the next highest multiple of \$1) equal to the amount of such stipend multiplied by the overall percentage (under section 5303 of title 5, United States Code) of the adjustment (if such adjustment is an increase) in the rates of pay under the General Schedule made effective in the fiscal year in which such school year ends.

(h) Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, while undergoing academic training, shall not be counted against any employment ceiling affecting the Department.

(i) Not later than March 1 of each year, the Secretary shall submit to the Congress a report providing, with respect to the preceding fiscal year—

(1) the number, and type of health profession training, of students receiving scholarships under the Scholarship Program;

(2) the educational institutions at which such students are receiving their training;

(3) the number of applications filed under this section in the school year beginning in such year and in prior school years;

(4) the amount of scholarship payments made for each of tuition, stipends, and other expenses, in the aggregate and at each educational institution for the school year beginning in such year and for prior school years;

(5)(A) the number, and type of health professions training, of individuals who have breached the contract under subsection (f) through any of the actions specified in subsection (a) or (b) of section 338E; and

(B) with respect to such individuals—

(i) the educational institutions with respect to which payments have been made or were to be made under the contract;

(ii) the amounts for which the individuals are liable to the United States under section 338E;

(iii) the extent of payment by the individuals of such amounts; and

(iv) if known, the basis for the decision of the individuals to breach the contract under subsection (f); and

(6) the effectiveness of the Secretary in recruiting health professionals to participate in the Scholarship Program, and in encouraging and assisting such professionals with respect to providing primary health services to health professional shortage areas after the completion of the period of obligated service under such Program.

SEC. 338B. [2541-1] NATIONAL HEALTH SERVICE CORPS LOAN REPAYMENT PROGRAM.

(a) **ESTABLISHMENT.**—The Secretary shall establish a program to be known as the National Health Service Corps Loan Repayment Program to assure, with respect to the provision of primary health services pursuant to section 331(a)(2)—

(1) an adequate supply of physicians, dentists, certified nurse midwives, certified nurse practitioners, and physician assistants; and

(2) if needed by the Corps, an adequate supply of other health professionals (including mental health professionals).

(b) **ELIGIBILITY.**—To be eligible to participate in the Loan Repayment Program, an individual must—

(1)(A) must¹ have a degree in medicine, osteopathic medicine, dentistry, or other health profession, or be certified as a nurse midwife, nurse practitioner², or physician assistant;

(B) be enrolled in an approved graduate training program in medicine, osteopathic medicine, dentistry, or other health profession; or

(C) be enrolled as a full-time student—

(i) in an accredited (as determined by the Secretary) educational institution in a State; and

(ii) in the final year of a course of a study or program, offered by such institution and approved by the Secretary, leading to a degree in medicine, osteopathic medicine, dentistry, or other health profession;

(2) be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the Corps; and

(3) submit to the Secretary an application for a contract described in subsection (f) (relating to the payment by the Secretary of the educational loans of the individual in consideration of the individual serving for a period of obligated service).

(c) **APPLICATION, CONTRACT, AND INFORMATION REQUIREMENTS.**—

¹So in original. The word "must" is redundant. See section 202(b)(1) of Public Law 101-597.

²So in original. Probably should be "practitioner". See *id.*

(1) SUMMARY AND INFORMATION.—In disseminating application forms and contract forms to individuals desiring to participate in the Loan Repayment Program, the Secretary shall include with such forms—

(A) a fair summary of the rights and liabilities of an individual whose application is approved (and whose contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled under section 338E in the case of the individual's breach of the contract; and

(B) information respecting meeting a service obligation through private practice under an agreement under section 338D and such other information as may be necessary for the individual to understand the individual's prospective participation in the Loan Repayment Program and service in the Corps.

(2) UNDERSTANDABILITY.—The application form, contract form, and all other information furnished by the Secretary under this subpart shall be written in a manner calculated to be understood by the average individual applying to participate in the Loan Repayment Program.

(3) AVAILABILITY.—The Secretary shall make such application forms, contract forms, and other information available to individuals desiring to participate in the Loan Repayment Program on a date sufficiently early to ensure that such individuals have adequate time to carefully review and evaluate such forms and information.

(4) RECRUITMENT AND RETENTION.—

(A) The Secretary shall distribute to health professions schools materials providing information on the Loan Repayment Program and shall encourage the schools to disseminate the materials to the students of the schools.

(B)(i) In the case of any health professional whose period of obligated service under the Loan Repayment Program is nearing completion, the Secretary shall encourage the individual to remain in a health professional shortage area and to continue providing primary health services.

(ii) During the period in which a health professional is planning and making the transition to private practice from obligated service under the Loan Repayment Program, the Secretary may provide assistance to the professional regarding such transition if the professional is remaining in a health professional shortage area and is continuing to provide primary health services.

(C) In the case of entities to which participants in the Loan Repayment Program are assigned under section 333, the Secretary shall encourage the entities to provide options with respect to assisting the participants in remaining in the health professional shortage areas involved, and in continuing to provide primary health services, after the period of obligated service under the Loan Repayment Program is completed. The options with respect to which the Secretary provides such encouragement may include options regarding the sharing of a single employment posi-

tion in the health professions by 2 or more health professionals, and options regarding the recruitment of couples where both of the individuals are health professionals.

(d)(1) Subject to section 333A, in providing contracts under the Loan Repayment Program—

(A) the Secretary shall consider the extent of the demonstrated interest of the applicants for the contracts in providing primary health services; and

(B) may consider such other factors regarding the applicants as the Secretary determines to be relevant to selecting qualified individuals to participate in such Program.

(2) In providing contracts under the Loan Repayment Program, the Secretary shall give priority—

(A) to any application for such a contract submitted by an individual whose training is in a health profession or specialty determined by the Secretary to be needed by the Corps;

(B) to any application for such a contract submitted by an individual who has (and whose spouse, if any, has) characteristics that increase the probability that the individual will continue to serve in a health professional shortage area after the period of obligated service pursuant to subsection (f) is completed; and

(C) subject to subparagraph (B), to any application for such a contract submitted by an individual who is from a disadvantaged background.

(e) APPROVAL REQUIRED FOR PARTICIPATION.—

(1) IN GENERAL.—An individual becomes a participant in the Loan Repayment Program only upon the Secretary and the individual entering into a written contract described in subsection (f).¹

(f) CONTENTS OF CONTRACTS.—The written contract (referred to in this subpart) between the Secretary and an individual shall contain—

(1) an agreement that—

(A) subject to paragraph (3), the Secretary agrees—

(i) to pay on behalf of the individual loans in accordance with subsection (g); and

(ii) to accept (subject to the availability of appropriated funds for carrying out sections 331 through 335 and section 337) the individual into the Corps (or for equivalent service as otherwise provided in this subpart); and

(B) subject to paragraph (3), the individual agrees—

(i) to accept loan payments on behalf of the individual;

(ii) in the case of an individual described in subsection (b)(1)(C), to maintain enrollment in a course of study or training described in such subsection until

¹So in original. See section 202(b)(2)(B) of Public Law 101-597 (104 Stat. 3024). There is no paragraph (2). Former paragraph (2) provided as follows:

(2) WRITTEN NOTICE.—The Secretary shall provide written notice to an individual promptly on—

(A) the Secretary's approving, under paragraph (1), of the individual's participation in the Loan Repayment Program; or

(B) the Secretary's disapproving an individual's participation in such Program.

the individual completes the course of study or training;

(iii) in the case of an individual described in subsection (b)(1)(C), while enrolled in such course of study or training, to maintain an acceptable level of academic standing (as determined under regulations of the Secretary by the educational institution offering such course of study or training); and

(iv) to serve for a time period (hereinafter in this subpart referred to as the "period of obligated service") equal to 2 years or such longer period as the individual may agree to, as a provider of primary health services in a health professional shortage area (designated under section 332) to which such individual is assigned by the Secretary as a member of the Corps or released under section 338D;

(2) a provision permitting the Secretary to extend for such longer additional periods, as the individual may agree to, the period of obligated service agreed to by the individual under paragraph (1)(B)(iv), including extensions resulting in an aggregate period of obligated service in excess of 4 years;

(3) a provision that any financial obligation of the United States arising out of a contract entered into under this subpart and any obligation of the individual that is conditioned thereon, is contingent on funds being appropriated for loan repayments under this subpart and to carry out the purposes of sections 331 through 335 and sections 337 and 338;

(4) a statement of the damages to which the United States is entitled, under section 338E for the individual's breach of the contract; and

(5) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with this subpart.

(g) PAYMENTS.—

(1) IN GENERAL.—A loan repayment provided for an individual under a written contract under the Loan Repayment Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual regarding the undergraduate or graduate education of the individual (or both), which loans were made for—

(A) tuition expenses;

(B) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the individual; or

(C) reasonable living expenses as determined by the Secretary.

(2) PAYMENTS FOR YEARS SERVED.—

(A) IN GENERAL.—For each year of obligated service that an individual contracts to serve under subsection (f) the Secretary may pay up to \$35,000 on behalf of the individual for loans described in paragraph (1). In making a determination of the amount to pay for a year of such serv-

ice by an individual, the Secretary shall consider the extent to which each such determination—

(i) affects the ability of the Secretary to maximize the number of contracts that can be provided under the Loan Repayment Program from the amounts appropriated for such contracts;

(ii) provides an incentive to serve in health professional shortage areas with the greatest such shortages; and

(iii) provides an incentive with respect to the health professional involved remaining in a health professional shortage area, and continuing to provide primary health services, after the completion of the period of obligated service under the Loan Repayment Program.

(B) REPAYMENT SCHEDULE.—Any arrangement made by the Secretary for the making of loan repayments in accordance with this subsection shall provide that any repayments for a year of obligated service shall be made no later than the end of the fiscal year in which the individual completes such year of service.

(3) TAX LIABILITY.—For the purpose of providing reimbursements for tax liability resulting from payments under paragraph (2) on behalf of an individual—

(A) the Secretary shall, in addition to such payments, make payments to the individual in an amount equal to 39 percent of the total amount of loan repayments made for the taxable year involved; and

(B) may make such additional payments as the Secretary determines to be appropriate with respect to such purpose.

(4) PAYMENT SCHEDULE.—The Secretary may enter into an agreement with the holder of any loan for which payments are made under the Loan Repayment Program to establish a schedule for the making of such payments.

(h) EMPLOYMENT CEILING.—Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, while undergoing academic or other training, shall not be counted against any employment ceiling affecting the Department.

(i) REPORTS.—Not later than March 1 of each year, the Secretary shall submit to the Congress a report providing, with respect to the preceding fiscal year—

(1) the total amount of loan payments made under the Loan Repayment Program;

(2) the number of applications filed under this section;

(3) the number, and type of health profession training, of individuals receiving loan repayments under such Program;

(4) the educational institution at which such individuals received their training;

(5) the total amount of the indebtedness of such individuals for educational loans as of the date on which the individuals become participants in such Program;

(6) the number of years of obligated service specified for such individuals in the initial contracts under subsection (f), and, in the case of individuals whose period of such service has been completed, the total number of years for which the individuals served in the Corps (including any extensions made for purposes of paragraph (2) of such subsection);

(7)(A) the number, and type of health professions training, of such individuals who have breached the contract under subsection (f) through any of the actions specified in subsection (a) or (b) of section 338E; and

(B) with respect to such individuals—

(i) the educational institutions with respect to which payments have been made or were to be made under the contract;

(ii) the amounts for which the individuals are liable to the United States under section 338E;

(iii) the extent of payment by the individuals of such amounts; and

(iv) if known, the basis for the decision of the individuals to breach the contract under subsection (f); and

(8) the effectiveness of the Secretary in recruiting health professionals to participate in the Loan Repayment Program, and in encouraging and assisting such professionals with respect to providing primary health services to health professional shortage areas after the completion of the period of obligated service under such Program.

OBLIGATED SERVICE

SEC. 338C. [254m] (a) Except as provided in section 338D, each individual who has entered into a written contract with the Secretary under section 338A or 338B shall provide service in the full-time clinical practice of such individual's profession as a member of the Corps for the period of obligated service provided in such contract.

(b)(1) If an individual is required under subsection (a) to provide service as specified in section 338A(f)(1)(B)(iv) or 338B(f)(1)(B)(iv) (hereinafter in this subsection referred to as "obligated service"), the Secretary shall, not later than ninety days before the date described in paragraph (5), determine if the individual shall provide such service—

(A) as a member of the Corps who is a commissioned officer in the Regular or Reserve Corps of the Service or who is a civilian employee of the United States, or

(B) as a member of the Corps who is not such an officer or employee,

and shall notify such individual of such determination.

(2) If the Secretary determines that an individual shall provide obligated service as a member of the Corps who is a commissioned officer in the Service or a civilian employee of the United States, the Secretary shall, not later than sixty days before the date described in paragraph (5), provide such individual with sufficient information regarding the advantages and disadvantages of service as such a commissioned officer or civilian employee to enable the

individual to make a decision on an informed basis. To be eligible to provide obligated service as a commissioned officer in the Service, an individual shall notify the Secretary, not later than thirty days before the date described in paragraph (5), of the individual's desire to provide such service as such an officer. If an individual qualifies for an appointment as such an officer, the Secretary shall, as soon as possible after the date described in paragraph (5), appoint the individual as a commissioned officer of the Regular or Reserve Corps of the Service and shall designate the individual as a member of the Corps.

(3) If an individual provided notice by the Secretary under paragraph (2) does not qualify for appointment as a commissioned officer in the Service, the Secretary shall, as soon as possible after the date described in paragraph (5), appoint such individual as a civilian employee of the United States and designate the individual as a member of the Corps.

(4) If the Secretary determines that an individual shall provide obligated service as a member of the Corps who is not an employee of the United States, the Secretary shall, as soon as possible after the date described in paragraph (5), designate such individual as a member of the Corps to provide such service.

(5)(A) In the case of the Scholarship Program, with respect to an individual receiving a degree from a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatry, or pharmacy, the date referred to in paragraphs (1) through (4) shall be the date on which the individual completes the training required for such degree, except that—

(i) at the request of such an individual with whom the Secretary has entered into a contract under section 338A prior to October 1, 1985, the Secretary shall defer such date until the end of the period of time (not to exceed the number of years specified in subparagraph (B) or such greater period as the Secretary, consistent with the needs of the Corps, may authorize) required for the individual to complete an internship, residency, or other advanced clinical training; and

(ii) at the request of such an individual with whom the Secretary has entered into a contract under section 338A on or after October 1, 1985, the Secretary may defer such date in accordance with clause (i).

(B)(i) In the case of the Scholarship Program, with respect to an individual receiving a degree from a school of medicine, osteopathic medicine, or dentistry, the number of years referred to in subparagraph (A)(i) shall be 3 years.

(ii) In the case of the Scholarship Program, with respect to an individual receiving a degree from a school of veterinary medicine, optometry, podiatry, or pharmacy, the number of years referred to in subparagraph (A)(i) shall be 1 year.

(C) No period of internship, residency, or other advanced clinical training shall be counted toward satisfying a period of obligated service under this subpart.

(D) In the case of the Scholarship Program, with respect to an individual receiving a degree from an institution other than a school referred to in subparagraph (A), the date referred to in paragraphs (1) through (4) shall be the date on which the individual

completes the academic training of the individual leading to such degree.

(E) In the case of the Loan Repayment Program, if an individual is required to provide obligated service under such Program, the date referred to in paragraphs (1) through (4)—

(i) shall be the date determined under subparagraph (A), (B), or (D) in the case of an individual who is enrolled in the final year of a course of study;

(ii) shall, in the case of an individual who is enrolled in an approved graduate training program in medicine, osteopathic medicine, dentistry, or other health profession, be the date the individual completes such training program; and

(iii) shall, in the case of an individual who has a degree in medicine, osteopathic medicine, dentistry, or other health profession and who has completed graduate training, be the date the individual enters into an agreement with the Secretary under section 338B.

(c) An individual shall be considered to have begun serving a period of obligated service—

(1) on the date such individual is appointed as an officer in a Regular or Reserve Corps of the Service or is designated as a member of the Corps under subsection (b)(3) or (b)(4), or

(2) in the case of an individual who has entered into an agreement with the Secretary under section 338D, on the date specified in such agreement,

whichever is earlier.

(d) The Secretary shall assign individuals performing obligated service in accordance with a written contract under the Scholarship Program to health professional shortage areas in accordance with sections 331 through 335 and sections 337 and 338. If the Secretary determines that there is no need in a health professional shortage area (designated under section 332) for a member of the profession in which an individual is obligated to provide service under a written contract and if such individual is an officer in the Service or a civilian employee of the United States, the Secretary may detail such individual to serve his period of obligated service as a full-time member of such profession in such unit of the Department as the Secretary may determine.

(e) Notwithstanding any other provision of this title, service of an individual under a National Research Service Award awarded under subparagraph (A) or (B) of section 472(a)(1)¹ shall be counted against the period of obligated service which the individual is required to perform under the Scholarship Program or under section 225 as in effect on September 30, 1977.

PRIVATE PRACTICE

SEC. 338D. [254n] (a) The Secretary shall, to the extent permitted by, and consistent with, the requirements of applicable State law, release an individual from all or part of his service obligation under section 338C(a) or under section 225 (as in effect on September 30, 1977) if the individual applies for such a release under this section and enters into a written agreement with the

¹See footnote 1 on page 47.

Secretary under which the individual agrees to engage for a period equal to the remaining period of his service obligation in the full-time private clinical practice (including service as a salaried employee in an entity directly providing health services) of his health profession—

(1) in the case of an individual who received a scholarship under the Scholarship Program or a loan repayment under the Loan Repayment Program and who is performing obligated service as a member of the Corps in a health professional shortage area on the date of his application for such a release, in the health professional shortage area in which such individual is serving on such date or in the case of an individual for whom a loan payment was made under the Loan Repayment Program and who is performing obligated service as a member of the Corps in a health professional shortage area on the date of the application of the individual for such a release, in the health professional shortage area selected by the Secretary; or

(2) in the case of any other individual, in a health professional shortage area (designated under section 332) selected by the Secretary.

(b) The written agreement described in subsection (a) shall—

(1) provide that during the period of private practice by an individual pursuant to the agreement—

(A) any person who receives health services provided by the individual in connection with such practice will be charged for such services at the usual and customary rate prevailing in the area in which such services are provided, except that if such person is unable to pay such charge, such person shall be charged at a reduced rate or not charged any fee; and

(B) the individual in providing health services in connection with such practice (i) shall not discriminate against any person on the basis of such person's ability to pay for such services or because payment for the health services provided to such person will be made under the insurance program established under part A or B of title XVIII of the Social Security Act or under a State plan for medical assistance approved under title XIX of such Act, and (ii) shall agree to accept an assignment under section 1842(b)(3)(B)(ii) of such Act for all services for which payment may be made under part B of title XVIII of such Act and enter into an appropriate agreement with the State agency which administers the State plan for medical assistance under title XIX of such Act to provide services to individuals entitled to medical assistance under the plan; and

(2) contain such additional provisions as the Secretary may require to carry out the purposes of this section.

For purposes of paragraph (1)(A), the Secretary shall by regulation prescribe the method for determining a person's ability to pay a charge for health services and the method of determining the amount (if any) to be charged such person based on such ability. The Secretary shall take such action as may be appropriate to en-

sure that the conditions of the written agreement prescribed by this subsection are adhered to.

(c) If an individual breaches the contract entered into under section 338A or 338B by failing (for any reason) to begin his service obligation in accordance with an agreement entered into under subsection (a) or to complete such service obligation, the Secretary may permit such individual to perform such service obligation as a member of the Corps.

(d) The Secretary may pay an individual who has entered into an agreement with the Secretary under subsection (a) an amount to cover all or part of the individual's expenses reasonably incurred in transporting himself, his family, and his possessions to the location of his private clinical practice.

(e) Upon the expiration of the written agreement under subsection (a), the Secretary may (notwithstanding any other provision of law) sell to the individual who has entered into an agreement with the Secretary under subsection (a), equipment and other property of the United States utilized by such individual in providing health services. Sales made under this subsection shall be made at the fair market value (as determined by the Secretary) of the equipment or such other property, except that the Secretary may make such sales for a lesser value to the individual if he determines that the individual is financially unable to pay the full market value.

(f) The Secretary may, out of appropriations authorized under section 338, pay to individuals participating in private practice under this section the cost of such individual's malpractice insurance and the lesser of—

- (1)(A) \$10,000 in the first year of obligated service;
- (B) \$7,500 in the second year of obligated service;
- (C) \$5,000 in the third year of obligated service; and
- (D) \$2,500 in the fourth year of obligated service; or

(2) an amount determined by subtracting such individual's net income before taxes from the income the individual would have received as a member of the Corps for each such year of obligated service.

(g) The Secretary shall, upon request, provide to each individual released from service obligation under this section technical assistance to assist such individual in fulfilling his or her agreement under this section.

BREACH OF SCHOLARSHIP CONTRACT OR LOAN REPAYMENT CONTRACT

SEC. 338E. [254o] (a)(1) An individual who has entered into a written contract with the Secretary under section 338A and who—

(A) fails to maintain an acceptable level of academic standing in the educational institution in which he is enrolled (such level determined by the educational institution under regulations of the Secretary),

(B) is dismissed from such educational institution for disciplinary reasons,

(C) voluntarily terminates the training in such an educational institution for which he is provided a scholarship under such contract, before the completion of such training, or

(D) fails to accept payment, or instructs the educational institution in which he is enrolled not to accept payment, in whole or in part, of a scholarship under such contract, in lieu of any service obligation arising under such contract, shall be liable to the United States for the amount which has been paid to him, or on his behalf, under the contract.

(2) An individual who has entered into a written contract with the Secretary under section 338B and who—

(A) in the case of an individual who is enrolled in the final year of a course of study, fails to maintain an acceptable level of academic standing in the educational institution in which such individual is enrolled (such level determined by the educational institution under regulations of the Secretary) or voluntarily terminates such enrollment or is dismissed from such educational institution before completion of such course of study; or

(B) in the case of an individual who is enrolled in a graduate training program, fails to complete such training program and does not receive a waiver from the Secretary under section 338B(b)(1)(B)(ii),

in lieu of any service obligation arising under such contract shall be liable to the United States for the amount that has been paid on behalf of the individual under the contract.

(b)(1)(A) Except as provided in paragraph (2), if (for any reason not specified in subsection (a) or section 338F(d))¹ an individual breaches his written contract by failing either to begin such individual's service obligation under section 338A in accordance with section 338C or 338D or to complete such service obligation, the United States shall be entitled to recover from the individual an amount determined in accordance with the formula

$$A=3\phi(t-s/t)$$

in which "A" is the amount the United States is entitled to recover, " ϕ " is the sum of the amounts paid under this subpart to or on behalf of the individual and the interest on such amounts which would be payable if at the time the amounts were paid they were loans bearing interest at the maximum legal prevailing rate, as determined by the Treasurer of the United States; "t" is the total number of months in the individual's period of obligated service; and "s" is the number of months of such period served by him in accordance with section 338C or a written agreement under section 338D.

(B)(i) Any amount of damages that the United States is entitled to recover under this subsection or under subsection (c) shall, within the 1-year period beginning on the date of the breach of the written contract (or such longer period beginning on such date as specified by the Secretary), be paid to the United States. Amounts not paid within such period shall be subject to collection through deductions in Medicare payments pursuant to section 1892 of the Social Security Act.

¹ So in original. Probably should be "section 338G(d)". See the redesignations made by section 204 of Public Law 101-597 (104 Stat. 3027).

(ii) If damages described in clause (i) are delinquent for 3 months, the Secretary shall, for the purpose of recovering such damages—

(I) utilize collection agencies contracted with by the Administrator of the General Services Administration; or

(II) enter into contracts for the recovery of such damages with collection agencies selected by the Secretary.

(iii) Each contract for recovering damages pursuant to this subsection shall provide that the contractor will, not less than once each 6 months, submit to the Secretary a status report on the success of the contractor in collecting such damages. Section 3718 of title 31, United States Code, shall apply to any such contract to the extent not inconsistent with this subsection.

(iv) To the extent not otherwise prohibited by law, the Secretary shall disclose to all appropriate credit reporting agencies information relating to damages of more than \$100 that are entitled to be recovered by the United States under this subsection and that are delinquent by more than 60 days or such longer period as is determined by the Secretary.

(2) If an individual is released under section 753 from a service obligation under section 225 (as in effect on September 30, 1977) and if the individual does not meet the service obligation incurred under section 753, subsection (f) of such section 225 shall apply to such individual in lieu of paragraph (1) of this subsection.

(c)(1) If (for any reason not specified in subsection (a) or section 338F(d))¹ an individual breaches the written contract of the individual under section 338B by failing either to begin such individual's service obligation in accordance with section 338C or 338D or to complete such service obligation, the United States shall be entitled to recover from the individual an amount equal to the sum of—

(A) in the case of a contract for a 2-year period of obligated service—

(i) the total of the amounts paid by the United States under section 338B(g)(2) on behalf of the individual for any period of obligated service; and

(ii) an amount equal to the unserved obligation penalty;

(B) in the case of a contract for a period of obligated service of greater than 2 years, and the breach occurs before the end of the first 2 years of such period—

(i) the total of the amounts paid by the United States under section 338B(g)(2) on behalf of the individual for any period of obligated service; and

(ii) an amount equal to the unserved obligation penalty; and

(C) in the case of a contract for a period of obligated service of greater than 2 years, and the breach occurs after the first 2 years of such period—

(i) the total of the amounts paid by the United States under section 338B(g)(2) on behalf of the individual for any period of obligated service not served; and

¹See footnote 1 on page 145.

(ii) if the individual breaching the contract failed to give the Secretary notice, that the individual intends to take action which constitutes a breach of the contract, at least 1 year (or such shorter period of time as the Secretary determines is adequate for finding a replacement) prior to the breach, \$10,000.

(2) For purposes of paragraph (1), the term "unserved obligation penalty" means the amount equal to the product of the number of months of obligated service that were not completed by an individual, multiplied by \$1,000, except that in any case in which the individual fails to serve 1 year, the unserved obligation penalty shall be equal to the full period of obligated service multiplied by \$1,000.

(3) The Secretary may waive, in whole or in part, the rights of the United States to recover amounts under this section in any case of extreme hardship or other good cause shown, as determined by the Secretary.

(4) Damages that the United States is entitled to recover shall be paid in accordance with subsection (b)(1)(B).

(d)(1) Any obligation of an individual under the Scholarship Program (or a contract thereunder) or the Loan Repayment Program (or a contract thereunder) for service or payment of damages shall be canceled upon the death of the individual.

(2) The Secretary shall by regulation provide for the partial or total waiver or suspension of any obligation of service or payment by an individual under the Scholarship Program (or a contract thereunder) or the Loan Repayment Program (or a contract thereunder) whenever compliance by the individual is impossible or would involve extreme hardship to the individual and if enforcement of such obligation with respect to any individual would be unconscionable.

(3)(A) Any obligation of an individual under the Scholarship Program (or a contract thereunder) or the Loan Repayment Program (or a contract thereunder) for payment of damages may be released by a discharge in bankruptcy under title 11 of the United States Code only if such discharge is granted after the expiration of the five-year period beginning on the first date that payment of such damages is required, and only if the bankruptcy court finds that nondischarge of the obligation would be unconscionable.

(B)(i) Subparagraph (A) shall apply to any financial obligation of an individual under the provision of law specified in clause (ii) to the same extent and in the same manner as such subparagraph applies to any obligation of an individual under the Scholarship or Loan Repayment Program (or contract thereunder) for payment of damages.

(ii) The provision of law referred to in clause (i) is subsection (f) of section 225 of this Act, as in effect prior to the repeal of such section by section 408(b)(1) of Public Law 94-484.

SEC. 338F. [254o-1] FUND REGARDING USE OF AMOUNTS RECOVERED FOR CONTRACT BREACH TO REPLACE SERVICES LOST AS RESULT OF BREACH.

(a) **ESTABLISHMENT OF FUND.**—There is established in the Treasury of the United States a fund to be known as the National Health Service Corps Member Replacement Fund (hereafter in this

section referred to as the "Fund"). The Fund shall consist of such amounts as may be appropriated under subsection (b) to the Fund. Amounts appropriated for the Fund shall remain available until expended.

(b) **AUTHORIZATION OF APPROPRIATIONS TO FUND.**—For each fiscal year, there is authorized to be appropriated to the Fund an amount equal to the sum of—

(1) the amount collected during the preceding fiscal year by the Federal Government pursuant to the liability of individuals under section 338E for the breach of contracts entered into under section 338A or 338B;

(2) the amount by which grants under section 338I have, for such preceding fiscal year, been reduced under subsection (g)(2)(B) of such section; and

(3) the aggregate of the amount of interest accruing during the preceding fiscal year on obligations held in the Fund pursuant to subsection (d) and the amount of proceeds from the sale or redemption of such obligations during such fiscal year.

(c) **USE OF FUND.**—

(1) **PAYMENTS TO CERTAIN HEALTH FACILITIES.**—Amounts in the Fund and available pursuant to appropriations Act may, subject to paragraph (2), be expended by the Secretary to make payments to any entity—

(A) to which a Corps member has been assigned under section 333; and

(B) that has a need for a health professional to provide primary health services as a result of the Corps member having breached the contract entered into under section 338A or 338B by the individual.

(2) **PURPOSE OF PAYMENTS.**—An entity receiving payments pursuant to paragraph (1) may expend the payments to recruit and employ a health professional to provide primary health services to patients of the entity, or to enter into a contract with such a professional to provide the services to the patients.

(d) **INVESTMENT.**—

(1) **IN GENERAL.**—The Secretary of the Treasury shall invest such amounts of the Fund as such Secretary determines are not required to meet current withdrawals from the Fund. Such investments may be made only in interest-bearing obligations of the United States. For such purpose, such obligations may be acquired on original issue at the issue price, or by purchase of outstanding obligations at the market price.

(2) **SALE OF OBLIGATIONS.**—Any obligation acquired by the Fund may be sold by the Secretary of the Treasury at the market price.

SPECIAL LOANS FOR FORMER CORPS MEMBERS TO ENTER PRIVATE PRACTICE

SEC. 338G. [254p] (a) The Secretary may, out of appropriations authorized under section 338, make one loan to a Corps member who has agreed in writing—

(1) to engage in the private full-time clinical practice of the profession of the member in a health professional shortage

area (designated under section 332) for a period of not less than 2 years which—

(A) in the case of a Corps member who is required to complete a period of obligated service under this subpart, begins not later than 1 year after the date on which such individual completes such period of obligated service; and

(B) in the case of an individual who is not required to complete a period of obligated service under this subpart, begins at such time as the Secretary considers appropriate;

(2) to conduct such practice in accordance with section 338D(b)(1); and

(3) to such additional conditions as the Secretary may require to carry out this section.

Such a loan shall be used to assist such individual in meeting the costs of beginning the practice of such individual's profession in accordance with such agreement, including the costs of acquiring equipment and renovating facilities for use in providing health services, and of hiring nurses and other personnel to assist in providing health services. Such loan may not be used for the purchase or construction of any building.

(b)(1) The amount of a loan under subsection (a) to an individual shall not exceed \$25,000.

(2) The interest rate for any such loan shall not exceed an annual rate of 5 percent.

(c) The Secretary may not make a loan under this section unless an application therefor has been submitted to, and approved by, the Secretary. The Secretary shall, by regulation, set interest rates and repayment terms for loans under this section.

(d) If the Secretary determines that an individual has breached a written agreement entered into under subsection (a), he shall, as soon as practicable after making such determination notify the individual of such determination. If within 60 days after the date of giving such notice, such individual is not practicing his profession in accordance with the agreement under such subsection and has not provided assurances satisfactory to the Secretary that he will not knowingly violate such agreement again, the United States shall be entitled to recover from such individual—

(1) in the case of an individual who has received a grant under this section (as in effect prior to October 1, 1984), an amount determined under section 338E(b), except that in applying the formula contained in such section “ ϕ ” shall be the sum of the amount of the grant made under subsection (a) to such individual and the interest on such amount which would be payable if at the time it was paid it was a loan bearing interest at the maximum legal prevailing rate, “ t ” shall be the number of months that such individual agreed to practice his profession under agreement, and “ s ” shall be the number of months that such individual practices his profession in accordance with such agreement; and

(2) in the case of an individual who has received a loan under this section, the full amount of the principal and interest owed by such individual under this section.

SEC. 338H. [254q] REPORT AND AUTHORIZATION OF APPROPRIATIONS.

(a) **REPORT.**—The Secretary shall report on March 1 of each year to the Committee on Labor and Human Resources of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Appropriations of the Senate and the House of Representatives on—

(1) the number of providers of health care who will be needed for the Corps during the 5 fiscal years beginning after the date the report is filed; and

(2) the number—

(A) of scholarships the Secretary proposes to provide under the Scholarship Program during such 5 fiscal years;

(B) of individuals for whom the Secretary proposes to make loan repayments under the Loan Repayment Program during such 5 fiscal years; and

(C) of individuals who have no obligation under section 338C and who the Secretary proposes to have as members of the Corps during such 5 fiscal years, in order to provide such number of health care providers.

(b) **FUNDING.**—

(1) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this subpart, there are authorized to be appropriated \$63,900,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 2000.

(2) **RESERVATION OF AMOUNTS.**—

(A) **SCHOLARSHIPS FOR NEW PARTICIPANTS.**—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary shall obligate not less than 30 percent for the purpose of providing contracts for scholarships under this subpart to individuals who have not previously received such scholarships.

(B) **SCHOLARSHIPS FOR FIRST-YEAR STUDY IN CERTAIN FIELDS.**—With respect to certification as a nurse practitioner, nurse midwife, or physician assistant, the Secretary shall, of the amounts appropriated under paragraph (1) for a fiscal year, obligate not less than 10 percent for the purpose of providing contracts for scholarships under this subpart to individuals who are entering the first year of study in a course of study or program described in subsection¹ 338A(b)(1)(B) that leads to such a certification. Amounts obligated under this subparagraph shall be in addition to amounts obligated under subparagraph (A).

SEC. 338I. [254q-1] GRANTS TO STATES FOR LOAN REPAYMENT PROGRAMS.

(a) **IN GENERAL.**—

(1) **AUTHORITY FOR GRANTS.**—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to States for the purpose of assisting the States in operating programs described in paragraph (2) in order to provide for the increased availability

¹ So in original. See Public Law 101-597. Probably should be "section".

of primary health services in health professional shortage areas.

(2) LOAN REPAYMENT PROGRAMS.—The programs referred to in paragraph (1) are, subject to subsection (c), programs of entering into contracts under which the State involved agrees to pay all or part of the principal, interest, and related expenses of the educational loans of health professionals in consideration of the professionals agreeing to provide primary health services in health professional shortage areas.

(3) DIRECT ADMINISTRATION BY STATE AGENCY.—The Secretary may not make a grant under paragraph (1) unless the State involved agrees that the program operated with the grant will be administered directly by a State agency.

(b) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the State agrees that, with respect to the costs of making payments on behalf of individuals under contracts made pursuant to paragraph (2) of such subsection, the State will make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount equal to not less than \$1 for each \$1 of Federal funds provided in the grant.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—In determining the amount of non-Federal contributions in cash that a State has provided pursuant to paragraph (1), the Secretary may not include any amounts provided to the State by the Federal Government.

(c) COORDINATION WITH FEDERAL PROGRAM.—

(1) ASSIGNMENTS FOR HEALTH PROFESSIONAL SHORTAGE AREAS UNDER FEDERAL PROGRAM.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that, in carrying out the program operated with the grant, the State will assign health professionals participating in the program only to public and nonprofit private entities located in and providing health services in health professional shortage areas.

(2) REMEDIES FOR BREACH OF CONTRACTS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that the contracts provided by the State pursuant to paragraph (2) of such subsection will provide remedies for any breach of the contracts by the health professionals involved.

(3) LIMITATION REGARDING CONTRACT INDUCEMENTS.—

(A) Except as provided in subparagraph (B), the Secretary may not make a grant under subsection (a) unless the State involved agrees that the contracts provided by the State pursuant to paragraph (2) of such subsection will not be provided on terms that are more favorable to health professionals than the most favorable terms that the Secretary is authorized to provide for contracts under the Loan Repayment Program under section 338B, including terms regarding—

(i) the annual amount of payments provided on behalf of the professionals regarding educational loans; and

(ii) the availability of remedies for any breach of the contracts by the health professionals involved.

(B) With respect to the limitation established in subparagraph (A) regarding the annual amount of payments that may be provided to a health professional under a contract provided by a State pursuant to subsection (a)(2), such limitation shall not apply with respect to a contract if—

(i) the excess of such annual payments above the maximum amount authorized in section 338B(g)(2)(A) for annual payments regarding contracts is paid solely from non-Federal contributions under subsection (b); and

(ii) the contract provides that the health professional involved will satisfy the requirement of obligated service under the contract solely through the provision of primary health services in a health professional shortage area that is receiving priority for purposes of section 333A(a)(1) and that is authorized to receive assignments under section 333 of individuals who are participating in the Scholarship Program under section 338A.

(d) RESTRICTIONS ON USE OF FUNDS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that the grant will not be expended—

(1) to conduct activities for which Federal funds are expended—

(A) within the State to provide technical or other non-financial assistance under subsection (f) of section 330;

(B) under a memorandum of agreement entered into with the State under subsection (h) of such section; or

(C) under a grant under section 338J; or

(2) for any purpose other than making payments on behalf of health professionals under contracts entered into pursuant to subsection (a)(2).

(e) REPORTS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees—

(1) to submit to the Secretary reports providing the same types of information regarding the program operated pursuant to such subsection as reports submitted pursuant to subsection (i) of section 338B provide regarding the Loan Repayment Program under such section; and

(2) to submit such a report not later than January 10 of each fiscal year immediately following any fiscal year for which the State has received such a grant.

(f) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out such subsection.

(g) NONCOMPLIANCE.—

(1) IN GENERAL.—The Secretary may not make payments under subsection (a) to a State for any fiscal year subsequent to the first fiscal year of such payments unless the Secretary determines that, for the immediately preceding fiscal year, the State has complied with each of the agreements made by the State under this section.

(2) REDUCTION IN GRANT RELATIVE TO NUMBER OF BREACHED CONTRACTS.—

(A) Before making a grant under subsection (a) to a State for a fiscal year, the Secretary shall determine the number of contracts provided by the State under paragraph (2) of such subsection with respect to which there has been an initial breach by the health professionals involved during the fiscal year preceding the fiscal year for which the State is applying to receive the grant.

(B) Subject to paragraph (3), in the case of a State with 1 or more initial breaches for purposes of subparagraph (A), the Secretary shall reduce the amount of a grant under subsection (a) to the State for the fiscal year involved by an amount equal to the sum of the expenditures of Federal funds made regarding the contracts involved and an amount representing interest on the amount of such expenditures, determined with respect to each contract on the basis of the maximum legal rate prevailing for loans made during the time amounts were paid under the contract, as determined by the Treasurer of the United States.

(3) WAIVER REGARDING REDUCTION IN GRANT.—The Secretary may waive the requirement established in paragraph (2)(B) with respect to the initial breach of a contract if the Secretary determines that such breach by the health professional involved was attributable solely to the professional having a serious illness.

(h) DEFINITIONS.—For purposes of this section, the term "State" means each of the several States.

(i) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of making grants under subsection (a), there is authorized to be appropriated \$10,000,000 for each of the fiscal years 1991 through 1995.

(2) AVAILABILITY.—Amounts appropriated under paragraph (1) shall remain available until expended.

SEC. 338J. [254r] GRANTS TO STATES FOR OPERATION OF OFFICES OF RURAL HEALTH.

(a) IN GENERAL.—The Secretary, action through the Director of the Office of Rural Health Policy (established in section 711 of the Social Security Act), may make grants to States for the purpose of improving health care in rural areas through the operation of State offices of rural health.

(b) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the State involved agrees, with respect to the costs to be incurred by the State in carrying out the purpose described in such subsection, to provide non-Fed-

eral contributions in cash toward such costs in an amount equal to—

(A) for the first fiscal year of payments under the grant, not less than \$1 for each \$3 of Federal funds provided in the grant;

(B) for any second fiscal year of such payments, not less than \$1 for each \$1 of Federal funds provided in the grant; and

(C) for any third fiscal year of such payments, not less than \$3 for each \$1 of Federal funds provided in the grant.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

(A) Subject to subparagraph (B), non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) The Secretary may not make a grant under subsection (a) unless the State involved agrees that—

(i) for the first fiscal year of payments under the grant, 100 percent or less of the non-Federal contributions required in paragraph (1) will be provided in the form of in-kind contributions;

(ii) for any second fiscal year of such payments, not more than 50 percent of such non-Federal contributions will be provided in the form of in-kind contributions; and

(iii) for any third fiscal year of such payments, such non-Federal contributions will be provided solely in the form of cash.

(c) CERTAIN REQUIRED ACTIVITIES.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that activities carried out by an office operated pursuant to such subsection will include—

(1) establishing and maintaining within the State a clearinghouse for collecting and disseminating information on—

(A) rural health care issues;

(B) research findings relating to rural health care; and

(C) innovative approaches to the delivery of health care in rural areas;

(2) coordinating the activities carried out in the State that relate to rural health care, including providing coordination for the purpose of avoiding redundancy in such activities; and

(3) identifying Federal and State programs regarding rural health, and providing technical assistance to public and non-profit private entities regarding participation in such programs.

(d) REQUIREMENT REGARDING ANNUAL BUDGET FOR OFFICE.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that, for any fiscal year for which the State receives such a grant, the office operated pursuant to sub-

section (a) will be provided with an annual budget of not less than \$50,000.

(e) CERTAIN USES OF FUNDS.—

(1) RESTRICTIONS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that—

(A) if research with respect to rural health is conducted pursuant to the grant, not more than 10 percent of the grant will be expended for such research; and

(B) the grant will not be expended—

(i) to provide health care (including providing cash payments regarding such care);

(ii) to conduct activities for which Federal funds are expended—

(I) within the State to provide technical and other nonfinancial assistance under subsection (f) of section 330;

(II) under a memorandum of agreement entered into with the State under subsection (h) of such section; or

(III) under a grant under section 338I;

(iii) to purchase medical equipment, to purchase ambulances, aircraft, or other vehicles, or to purchase major communications equipment;

(iv) to purchase or improve real property; or

(v) to carry out any activity regarding a certificate of need.

(2) AUTHORITIES.—Activities for which a State may expend a grant under subsection (a) include—

(A) paying the costs of establishing an office of rural health for purposes of subsection (a);

(B) subject to paragraph (1)(B)(ii)(III), paying the costs of any activity carried out with respect to recruiting and retaining health professionals to serve in rural areas of the State; and

(C) providing grants and contracts to public and non-profit private entities to carry out activities authorized in this section.

(f) REPORTS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees—

(1) to submit to the Secretary reports containing such information as the Secretary may require regarding activities carried out under this section by the State; and

(2) to submit such a report not later than January 10 of each fiscal year immediately following any fiscal year for which the State has received such a grant.

(g) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out such subsection.

(h) NONCOMPLIANCE.—The Secretary may not make payments under subsection (a) to a State for any fiscal year subsequent to the first fiscal year of such payments unless the Secretary determines

that, for the immediately preceding fiscal year, the State has complied with each of the agreements made by the State under this section.

(i) **DEFINITIONS.**—For purposes of this section, the term “State” means each of the several States.

(j) **AUTHORIZATION OF APPROPRIATIONS.**—

(1) **IN GENERAL.**—For the purpose of making grants under subsection (a), there are authorized to be appropriated \$3,000,000 for fiscal year 1991, \$4,000,000 for fiscal year 1992, and \$3,000,000 for fiscal year 1993.

(2) **AVAILABILITY.**—Amounts appropriated under paragraph (1) shall remain available until expended.

(k) **TERMINATION OF PROGRAM.**—No grant may be made under this section after the aggregate amounts appropriated under subsection (j)(1) are equal to \$10,000,000.

SEC. 338K. [254s] NATIVE HAWAIIAN HEALTH SCHOLARSHIPS.

(a) Subject to the availability of funds appropriated under the authority of subsection (d), the Secretary shall provide scholarship assistance, pursuant to a contract with the Kamehameha Schools/ Bishop Estate, to students who—

(1) meet the requirements of section 338A(b), and

(2) are Native Hawaiians.

(b)(1) The scholarship assistance provided under subsection (a) shall be provided under the same terms and subject to the same conditions, regulations, and rules that apply to scholarship assistance provided under section 338A.

(2) The Native Hawaiian Health Scholarship program shall not be administered by or through the Indian Health Service.

(c) For purposes of this section, the term “Native Hawaiian” means any individual who is—

(1) a citizen of the United States,

(2) a resident of the State of Hawaii, and

(3) a descendant of the aboriginal people, who prior to 1778, occupied and exercised sovereignty in the area that now constitutes the State of Hawaii, as evidenced by—

(A) genealogical records,

(B) Kupuna (elders) or Kama’aina (long-term community residents) verification, or

(C) birth records of the State of Hawaii.

(d) There are authorized to be appropriated \$1,800,000 for each of the fiscal years 1990, 1991, and 1992 for the purpose of funding the scholarship assistance provided under subsection (a).

SEC. 338L. [254t] DEMONSTRATION GRANTS TO STATES FOR COMMUNITY SCHOLARSHIP PROGRAMS.

(a) **IN GENERAL.**—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to States for the purpose of carrying out demonstration programs to increase the availability of primary health care in urban and rural health manpower¹ shortage areas through assist-

¹So in original. Section 401(b)(2) (the first subsection (b)) of Public Law 101-597 amended various provisions of this Act by striking the term “health manpower shortage area” and inserting the term “health professional shortage area”, but such amendments were not made to section 338L. (Section 338L was added by section 8 of Public Law 101-527.)

ing community organizations of such areas in educating individuals to serve as health professionals in such areas.

(b) CERTAIN REQUIREMENTS FOR STATES.—

(1) MINIMUM QUALIFICATIONS.—The Secretary may not make a grant under subsection (a) unless the State involved will, under any provision of this Act other than subsection (a), receive 1 or more grants, cooperative agreements, or contracts for the fiscal year for which the State is applying pursuant to subsection (h) to receive a grant under subsection (a).

(2) ADMINISTRATION OF PROGRAM.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that the program carried out by the State with the grant will be administered directly by a single State agency.

(c) GRANTS BY STATES TO COMMUNITY ORGANIZATIONS FOR PROVISION OF SCHOLARSHIP CONTRACTS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees, subject to subsections (d) and (e), to carry out the purpose described in subsection (a) only through operating a program in which the State makes grants to community organizations located in health manpower¹ shortage areas in order to assist the organizations with the costs of entering into contracts under which—

(1) the community organizations agree to provide scholarships to individuals for attendance at health professions schools; and

(2) the individuals agree to provide, in the health manpower¹ shortage areas in which the community organizations are located, primary health care for—

(A) a number of years equal to the number of years for which the scholarships are provided, or for a period of 2 years, whichever period is greater; or

(B) such greater period of time as the individuals and the community organizations may agree.

(d) REQUIREMENT OF STATE AND LOCAL MATCHING FUNDS.—

(1) IN GENERAL.—With respect to the costs of providing any scholarship pursuant to subsection (c), the Secretary may not make a grant under subsection (a) unless the State involved agrees that—

(A) 40 percent of the costs of the scholarship will be paid from the grant made under subsection (a) to the State; and

(B) 60 percent of such costs will be paid from non-Federal contributions made in cash by both the State and the community organization through which the scholarship is provided, subject to—

(i) the State making available through such contributions not less than 15 percent, nor more than 25 percent, of such costs; and

(ii) the community organization making available through such contributions not less than 35 percent, nor more than 45 percent, of such costs.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTIONS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that, in determining the amount of non-Federal contributions that have been

provided in cash for purposes of paragraph (1), the State will not include any amounts provided by the Federal Government to the State or community organization involved, or to any other entity.

(3) USE OF DONATIONS.—Non-Federal contributions required in paragraph (1) may be provided directly by the State and community organization involved, and may be provided through donations from public and private entities.

(e) SPECIFICATIONS REGARDING SCHOLARSHIP CONTRACT.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that the State will make a grant to a community organization for a contract described in subsection (c) only if—

(1) the individual who is to receive the scholarship under the contract is a resident of the health manpower¹ shortage area in which the community organization is located;

(2) the individual is enrolled or accepted for enrollment as a full-time student in a health professions school that is approved by the Secretary for purposes of this section;

(3) the individual agrees to maintain an acceptable level of academic standing at the school (as determined by the school in accordance with regulations issued by the Secretary for purposes of section 338A(f)(1)(B)(iii));

(4) the individual and the community organization agree that the scholarship provided pursuant to the contract—

(A) will be expended only for—

(i) tuition expenses, other reasonable educational expenses, and reasonable living expenses incurred in attendance at the school; and

(ii) payment to the individual of a monthly stipend of not more than the amount authorized for purposes of section 338A(g)(1)(B); and

(B) will not, for any year of such attendance for which the scholarship is provided, be in an amount exceeding the total amount required for the year for the purposes authorized in subparagraph (A);

(5) the individual agrees to meet the educational and licensure requirements necessary to be a physician, certified nurse practitioner, certified nurse midwife, or physician assistant; and

(6) the individual agrees that, in providing primary health care pursuant to the scholarship, the individual—

(A) will not, in the case of an individual seeking such care, discriminate against the individual on the basis of the ability of the individual to pay for such care or on the basis that payment for such care will be made pursuant to the program established in title XVIII of the Social Security Act or pursuant to the program established in title XIX of such Act; and

(B) will accept assignment under section 1842(b)(3)(B)(ii) of the Social Security Act for all services for which payment may be made under part B of title XVIII of such Act, and will enter into an appropriate

¹ See footnote 1 on page 156.

agreement with the State agency that administers the State plan for medical assistance under title XIX of such Act to provide service to individuals entitled to medical assistance under the plan.

(f) **REPORTS TO SECRETARY.**—The Secretary may not make a grant under subsection (a) unless the State involved agrees—

(1) for each fiscal year for which such a grant is received by the State, to submit to the Secretary a report—

(A) identifying the community organizations providing scholarships pursuant to subsection (c) and the health manpower¹ shortage areas in which the organizations are located;

(B) providing the names of individuals receiving the scholarships, the health professions in which the individuals will engage pursuant to the scholarships, the number of years of service the individuals are obligated to provide pursuant to the scholarships, and the extent of compliance with the contracts under subsection (c) on the part of the individuals and the community organizations; and

(C) providing such information as the Secretary may determine to be necessary for carrying out this section; and

(2) to submit each such report not later than January 10 of the fiscal year immediately following the fiscal year for which the report is prepared.

(g) **ESTIMATES REGARDING ALLOCATIONS BETWEEN URBAN AND RURAL AREAS.**—The Secretary may not make a grant under subsection (a) unless the State involved submits to the Secretary, as part of the application required in subsection (h), an estimate of the amount of the grant that will be expended regarding the provision of primary health care in urban health manpower¹ shortage areas of the State, and an estimate of the amount of the grant that will be expended regarding the provision of such care in rural health manpower¹ shortage areas of the State.

(h) **REQUIREMENT OF APPLICATION.**—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(i) **NONCOMPLIANCE.**—

(1) **IN GENERAL.**—The Secretary may not make payments under subsection (a) to a State for any fiscal year subsequent to the first fiscal year of such payments unless the Secretary determines that, for the immediately preceding fiscal year, the State has complied with each of the agreements made by the State under this section.

(2) **REDUCTION IN GRANT RELATIVE TO NUMBER OF BREACHED CONTRACTS.**—

(A) Before making a grant under subsection (a) to a State for a fiscal year, the Secretary shall determine the number of contracts provided under subsection (c) with re-

¹ See footnote 1 on page 156.

spect to which there has been an initial breach by the community organizations or individuals involved during the fiscal year preceding the fiscal year for which the State is applying to receive the grant.

(B) In the case of a State with 1 or more initial breaches for purposes of subparagraph (A), the Secretary shall reduce the amount of a grant under subsection (a) to the State for the fiscal year involved by an amount equal to the sum of—

(i) an amount equal to the expenditures of Federal funds made regarding the contracts involved; and

(ii) an amount representing interest on the amount of such expenditures, determined with respect to each contract on the basis of the maximum legal rate prevailing for loans made during the time amounts were paid under the contract, as determined by the Treasurer of the United States.

(C) If a State is not receiving a grant under subsection (a) for a fiscal year for which a reduction under subparagraph (B) would have been made in the event that the State had received such a grant, the Secretary shall reduce the amount of payments due to the State under other grants, cooperative agreements, or contracts under this Act by the amount specified in such subparagraph.

(D) With respect to contracts provided under subsection (c), the Secretary may carry out this paragraph on the basis of information submitted by the States involved, or on the basis of information collected through such other means as the Secretary determines to be appropriate.

(j) REPORTS TO CONGRESS.—

(1) IN GENERAL.—Each fiscal year the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report summarizing information received by the Secretary under subsection (f) for the preceding fiscal year.

(2) DATE FOR SUBMISSION.—With respect to a fiscal year, the report required in paragraph (1) shall be submitted for purposes of such paragraph by not later than the date on which the report required in section 338A(i) is required to be submitted for purposes of such section.

(k) DEFINITIONS.—For purposes of this section:

(1) COMMUNITY ORGANIZATION.—The term “community organization” means a public or nonprofit private entity.

(2) PRIMARY HEALTH CARE.—The term “primary health care” means health services regarding family medicine, internal medicine, pediatrics, or obstetrics and gynecology, that are provided by physicians, certified nurse practitioners, certified nurse midwives, or physician assistants.

(3) STATE.—The term “State” means each of the several States and the District of Columbia.

(l) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of making grants under subsection (a), there are authorized to

be appropriated \$5,000,000 for fiscal year 1991, \$10,000,000 for fiscal year 1992, and such sums as may be necessary for fiscal year 1993.

(2) AVAILABILITY.—Amounts appropriated under paragraph (1) shall remain available until expended.

(3) ALLOCATIONS FOR RURAL AREAS.—

(A) In carrying out subsection (a), the Secretary shall, to the extent practicable, ensure that not less than 50 percent of the amounts appropriated under paragraph (1) are, in the aggregate, expended for making grants pursuant to subsection (c) to community organizations that are located in rural health manpower¹ shortage areas.

(B) Subparagraph (A) may not be construed to prohibit the Secretary from making grants under subsection (a) to States in which no rural health manpower¹ shortage areas are located.

(C) With respect to any fiscal year for which the Secretary is unable to comply with subparagraph (A), the Secretary shall, not later than April 1 of the subsequent fiscal year, submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report stating the fact of such noncompliance and an explanation of the reasons underlying such noncompliance.

Subpart IV—Home Health Services

HOME HEALTH SERVICES

SEC. 339. [255] (a)(1) For the purpose of encouraging the establishment and initial operation of home health programs to provide home health services in areas in which such services are inadequate or not readily accessible, the Secretary may, in accordance with the provisions of this section, make grants to public and non-profit private entities and loans to proprietary entities to meet the initial costs of establishing and operating such home health programs. Such grants and loans may include funds to provide training for paraprofessionals (including homemaker home health aides) to provide home health services.

(2) In making grants and loans under this subsection, the Secretary shall—

(A) consider the relative needs of the several States for home health services;

(B) give preference to areas in which a high percentage of the population proposed to be served is composed of individuals who are elderly, medically indigent, or disabled; and

(C) give special consideration to areas with inadequate means of transportation to obtain necessary health services.

(3)(A) No loan may be made to a proprietary entity under this section unless the application of such entity for such loan contains assurances satisfactory to the Secretary that—

(i) at the time the application is made the entity is fiscally sound;

¹See footnote 1 on page 156.

(ii) the entity is unable to secure a loan for the project for which the application is submitted from non-Federal lenders at the rate of interest prevailing in the area in which the entity is located; and

(iii) during the period of the loan, such entity will remain fiscally sound.

(B) Loans under this section shall be made at an interest rate comparable to the rate of interest prevailing on the date the loan is made with respect to the marketable obligations of the United States of comparable maturities, adjusted to provide for administrative costs.

(4) Applications for grants and loans under this subsection shall be in such form and contain such information as the Secretary shall prescribe.

(5) There are authorized to be appropriated for grants and loans under this subsection \$5,000,000 for each of the fiscal years ending on September 30, 1983, September 30, 1984, September 30, 1985, September 30, 1986, and September 30, 1987.

(b)(1) The Secretary may make grants to and enter into contracts with public and private entities to assist them in developing appropriate training programs for paraprofessionals (including homemaker home health aides) to provide home health services.

(2) Any program established with a grant or contract under this subsection to train homemaker home health aides shall—

(A) extend for at least forty hours, and consist of classroom instruction and at least twenty hours (in the aggregate) of supervised clinical instruction directed toward preparing students to deliver home health services;

(B) be carried out under appropriate professional supervision and be designed to train students to maintain or enhance the personal care of an individual in his home in a manner which promotes the functional independence of the individual; and

(C) include training in—

(i) personal care services designed to assist an individual in the activities of daily living such as bathing, exercising, personal grooming, and getting in and out of bed; and

(ii) household care services such as maintaining a safe living environment, light housekeeping, and assisting in providing good nutrition (by the purchasing and preparation of food).

(3) In making grants and entering into contracts under this subsection, special consideration shall be given to entities which establish or will establish programs to provide training for persons fifty years of age and older who wish to become paraprofessionals (including homemaker home health aides) to provide home health services.

(4) Applications for grants and contracts under this subsection shall be in such form and contain such information as the Secretary shall prescribe.

(5) There are authorized to be appropriated for grants and contracts under this subsection \$2,000,000 for each of the fiscal years ending September 30, 1983, September 30, 1984, September 30, 1985, September 30, 1986, and September 30, 1987.

(c) The Secretary shall report to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives on or before January 1, 1984, with respect to—

(1) the impact of grants made and contracts entered into under subsections (a) and (b) (as such subsections were in effect prior to October 1, 1981);

(2) the need to continue grants and loans under subsections (a) and (b) (as such subsections are in effect on the day after the date of enactment of the Orphan Drug Act); and

(3) the extent to which standards have been applied to the training of personnel who provide home health services.

(d) For purposes of this section, the term "home health services" has the meaning prescribed for the term by section 1861(m) of the Social Security Act.

Subpart V—Health Services for the Homeless

GRANT PROGRAM FOR CERTAIN HEALTH SERVICES FOR THE HOMELESS

SEC. 340. [256] (a) ESTABLISHMENT.—(1) The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make grants for the purpose of enabling grantees, directly or through contracts, to provide for the delivery of health services to homeless individuals.

(2) In carrying out the program established in paragraph (1), the Administrator shall consult with the Director of the National Institute on Alcohol Abuse and Alcoholism and with the Director of the National Institute of Mental Health.

(b) MINIMUM QUALIFICATIONS OF GRANTEEES.—(1) Subject to paragraph (2), the Secretary may not make a grant under subsection (a) to an applicant unless—

(A) the applicant is a public or nonprofit private entity;

(B) the applicant has the capacity to effectively administer a grant under subsection (a); and

(C) in the case of any health service that is covered in the State plan approved under title XIX of the Social Security Act for the State involved—

(i) the applicant for the grant will provide the health service directly, and the applicant has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the applicant for the grant will enter into an agreement with an organization under which the organization will provide the health service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(2)(A) In the case of an organization making an agreement under paragraph (1)(C)(ii) regarding the provision of health services under subsection (a), the requirement established in such paragraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(B) A determination by the Secretary of whether an organization referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(c) PREFERENCES IN MAKING GRANTS.—The Secretary shall, in making grants under subsection (a), give preference to qualified applicants that—

(1)(A) are experienced in the direct delivery of primary health services to homeless individuals or medically underserved populations; or

(B) are experienced in the treatment of substance abuse in homeless individuals or medically underserved populations; and

(2) agree to provide for health services to homeless individuals through both public entities and private organizations.

(d) REQUIREMENT OF SUBMISSION OF APPLICATION CONTAINING CERTAIN AGREEMENTS.—(1) The Secretary may not make a grant under subsection (a) to an applicant unless the applicant has submitted to the Secretary an application for the grant containing agreements in accordance with—

(A) subsection (e)(1)(A)(ii), relating to the provision of matching funds;

(B) subsection (f), relating to the provision of certain health services;

(C) subsection (i), relating to restrictions on the use of funds;

(D) subsection (j), relating to a limitation on charges for services;

(E) subsection (k), relating to the administration of grants; and

(F) subsection (l), relating to a limitation on administrative expenses.

(2) An application required in paragraph (1) shall, with respect to agreements required to be contained in the application, provide assurances of compliance satisfactory to the Secretary and shall otherwise be in such form, be made in such manner, and contain such information in addition to information required in paragraph (1) as the Secretary determines to be necessary to carry out this section.

(e) REQUIREMENT OF PROVISION OF MATCHING FUNDS.—(1)(A) The Secretary may not make a grant under subsection (a) to an applicant—

(i) in an amount exceeding 75 percent of the costs of providing health services for the first fiscal year of payments under the grant and 66⅔ percent of the costs of providing such services for any subsequent fiscal year of payments under the grant; and

(ii) unless the applicant agrees that the applicant will make available, directly or through donations to the applicant, non-Federal contributions toward such costs in an amount equal to not less than \$1 (in cash or in kind under subparagraph (B)) for each \$3 of Federal funds provided for the first fiscal year of payments under the grant and not less than \$1

(in cash or in kind under such subparagraph) for each \$2 of Federal funds provided for any subsequent fiscal year of payments under the grant.

(B)(i) Non-Federal contributions required in subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(ii) Such determination may not include any cash or in-kind contributions that, prior to February 26, 1987, were made available by any public or private entity for the purpose of assisting homeless individuals (including assistance other than the provision of health services).

(2) The Secretary may waive the requirement established in paragraph (1)(A) if the applicant involved is a nonprofit private entity and the Secretary determines that it is not feasible for the applicant to comply with such requirement.

(f) REQUIREMENT OF PROVISION OF CERTAIN HEALTH SERVICES.—The Secretary may not make a grant under subsection (a) to an applicant unless the applicant agrees that the applicant will, directly or through contract—

(1) provide health services at locations accessible to homeless individuals;

(2) provide to homeless individuals, at all hours, emergency health services;

(3) refer homeless individuals as appropriate to medical facilities for necessary hospital services;

(4) refer for mental health services homeless individuals who are mentally ill to entities that provide such services, unless the applicant will provide such services pursuant to subsection (g);

(5) provide outreach services to inform homeless individuals of the availability of health services; and

(6) aid homeless individuals in establishing eligibility for assistance, and in obtaining services, under entitlement programs.

(g) OPTIONAL PROVISION OF CERTAIN SERVICES.—A grantee under subsection (a) may expend amounts received pursuant to such subsection for the purpose of providing to homeless individuals mental health services, dental services (including dentures), services with respect to vision, and podiatry services.

(h) TEMPORARY CONTINUED PROVISION OF SERVICES TO CERTAIN FORMER HOMELESS INDIVIDUALS.—If any grantee under subsection (a) has provided services described in subsection (f) or (g) to a homeless individual, any such grantee may, notwithstanding that the individual is no longer homeless as a result of becoming a resident in permanent housing, expend the grant to continue to provide such services to the individual for not more than 12 months.

(i) RESTRICTIONS ON USE OF GRANT FUNDS.—(1) The Secretary may not, except as provided in paragraph (2), make a grant under subsection (a) to an applicant unless the applicant agrees that

amounts received pursuant to such subsection will not, directly or through contract, be expended—

(A) for any purpose other than the purposes described in subsections (a) and (g);

(B) to provide inpatient services, except with respect to residential treatment for substance abuse provided in settings other than hospitals;

(C) to make cash payments to intended recipients of health services or mental health services; or

(D) to purchase or improve real property (other than minor remodeling of existing improvements to real property) or to purchase major medical equipment.

(2) If the Secretary finds that the purpose described in subsection (a) cannot otherwise be carried out, the Secretary may, with respect to an otherwise qualified applicant, waive the restriction established in paragraph (1)(D).

(j) **LIMITATION ON CHARGES FOR SERVICES.**—The Secretary may not make a grant under subsection (a) to an applicant unless the applicant agrees that, whether health services are provided directly or through contract—

(1) health services under the grant will be provided without regard to ability to pay for the health services; and

(2) if a charge is imposed for the delivery of health services, such charge—

(A) will be made according to a schedule of charges that is made available to the public;

(B) will not be imposed on any homeless individual with an income less than the official poverty level; and

(C) will be adjusted to reflect the income and resources of the homeless individual involved.

(k) **REQUIREMENTS WITH RESPECT TO ADMINISTRATION.**—The Secretary may not make a grant under subsection (a) to an applicant unless the applicant—

(1) agrees to establish such procedures for fiscal control and fund accounting as may be necessary to ensure proper disbursement and accounting with respect to the grant;

(2) agrees to establish an ongoing program of quality assurance with respect to the health services provided under the grant;

(3) agrees to ensure the confidentiality of records maintained on homeless individuals receiving health services under the grant;

(4) with respect to providing health services to any population of homeless individuals a substantial portion of which has a limited ability to speak the English language—

(A) has developed and has the ability to carry out a reasonable plan to provide health services under the grant through individuals who are able to communicate with the population involved in the language and cultural context that is most appropriate; and

(B) has designated at least one individual, fluent in both English and the appropriate language, to assist in carrying out the plan; and

(5) agrees to submit to the Secretary an annual report that describes the utilization and costs of health services provided under the grant and that provides such other information as the Secretary determines to be appropriate.

(l) **LIMITATION ON ADMINISTRATIVE EXPENSES OF GRANTEE.**—The Secretary may not make a grant under subsection (a) to an applicant unless the applicant agrees that the applicant will not expend more than 10 percent of amounts received pursuant to such subsection for the purpose of administering the grant.

(m) **USE OF GRANT FUNDS FOR REFERRALS TO CERTAIN ADVOCACY SYSTEMS.**—A grantee under subsection (a) may, with respect to title I of the Protection and Advocacy for Mentally Ill Individuals Act of 1986, expend amounts received under subsection (a) for the purpose of referring homeless individuals who are chronically mentally ill, and who are eligible under such Act, to systems that provide advocacy services under such Act.

(n) **USE OF SELF-HELP ORGANIZATIONS.**—Any grantee under subsection (a) may provide health services through contracts with nonprofit self-help organizations that—

(1) are established and managed by current and former recipients of mental health services, or substance abuse services, who have been homeless individuals; and

(2) with respect to the provision of health services described in subsection (b)(3), are organizations qualified under subparagraph (B) of such subsection.

(o) **TECHNICAL ASSISTANCE.**—(1) The Secretary may, without charge to any grantee under subsection (a), provide technical assistance to any such grantee with respect to the planning, development, and operation of programs to carry out the purpose described in such subsection. The Secretary may provide such technical assistance directly, through contract, or through grants.

(2) Of the amounts appropriated pursuant to subsection (q)(1) for a fiscal year, the Secretary may expend not more than \$2,000,000 for the purpose of carrying out paragraph (1).

(p) **ANNUAL REPORTS BY SECRETARY.**—Not later than January 10 of each year, the Secretary shall submit to the Congress a report describing the utilization and costs of health services provided under subsection (a) during the immediately preceding fiscal year.

(q) **FUNDING.**—(1) There are authorized to be appropriated to carry out this section \$70,000,000 for fiscal year 1991, \$80,000,000 for fiscal year 1992, and such sums as may be necessary for each of the fiscal years 1993 and 1994.

(2) Amounts received by a grantee pursuant to subsection (a) remaining unobligated at the end of the fiscal year in which the amounts were received shall remain available to the grantee during the succeeding fiscal year for the purpose described in such subsection.

(r) **DEFINITIONS.**—For purposes of this section:

(1) The term “health services” means primary health services and substance abuse services.

(2) The term “homeless individual” means an individual who lacks housing (without regard to whether the individual is a member of a family), including an individual whose primary residence during the night is a supervised public or private fa-

cility that provides temporary living accommodations and an individual who is a resident in transitional housing.

(3) The term "medically underserved population" has the meaning given such term in section 330(b)(3).

(4) The term "official poverty level" means the nonfarm income official poverty line defined by the Office of Management and Budget and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(5) The term "organization" includes individuals, corporations, partnerships, companies, and associations.

(6) The term "primary health services" has the meaning given such term in section 330(b)(1).

(7) The term "substance abuse" has the meaning given such term in section 536(4).¹

(8) The term "substance abuse services" includes detoxification and residential treatment for substance abuse provided in settings other than hospitals.

(s) GRANTS REGARDING OUTREACH AND PRIMARY HEALTH SERVICES FOR HOMELESS CHILDREN.—

(1) The Secretary may make grants to entities specified in paragraph (2) for the purpose of enabling the entities, directly or through contracts, to carry out demonstration programs—

(A) to provide comprehensive primary health services to homeless children and to children at imminent risk of homelessness, including such services provided through mobile medical units;

(B) to provide referrals for the provision of appropriate health services, social services, and education services to children receiving services under subparagraph (A) (including referrals regarding hospitals, the programs of sections 329 and 330, the program of the Head Start Act (and other programs providing education services), and programs regarding the prevention and treatment of child abuse); and

(C) to provide outreach services to identify children who are homeless and to inform the parents (or other guardians) of the children of the availability of services from the grantees and from the entities or programs specified in subparagraph (B).

(2) The entities referred to in paragraph (1) are—

(A) grantees under subsection (a), and other public and nonprofit private entities (other than children's hospitals) that provide primary health services, and substance abuse services, to a substantial number of homeless individuals; and

(B) public and nonprofit private children's hospitals that provide primary health services to a substantial number of such individuals.

(3)(A) The Secretary may not make a grant under paragraph (1) to a hospital unless the hospital agrees, with respect to the costs of providing services under such paragraph, to

¹So in original. Probably should be "section 534(4)". See the amendments made by section 511 of Public Law 101-645 (104 Stat. 4726).

make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than \$1 for each \$1 of Federal funds provided in the grant.

(B) Non-Federal contributions required in subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(4) The Secretary may not make a grant under paragraph (1) unless the applicant for the grant agrees that subsections (b)(3), (h), (i), and (j) will apply to the grant to the same extent and in the same manner as such subsections apply to any grant under subsection (a). For purposes of subsection (i)(1)(D) (including as applied to this subsection by the preceding sentence), mobile medical units shall be considered to be major medical equipment.

(5) The Secretary may not make a grant under paragraph (1) unless the applicant for the grant agrees to collect such data as the Secretary determines to be necessary for assessing the efficacy of services provided under paragraph (1) to homeless children.

(6) The Secretary may not make a grant under paragraph (1) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this subsection.

(7) In making grants under paragraph (1), the Secretary shall take into account the needs of homeless children in rural areas.

(8) For the purpose of carrying out this subsection, there is authorized to be appropriated \$5,000,000 for each of the fiscal years 1991 through 1993.

(t) **INFANT MORTALITY AND MORBIDITY.**—

(1) **IN GENERAL.**—The Secretary may make grants to grantees under subsection (a) for the purpose of assisting such grantees in—

(A) providing comprehensive health care and support services for the reduction of (i) the incidence of infant mortality, and (ii) morbidity among children who are less than 3 years of age; and

(B) developing and coordinating service and referral arrangements between such grantees and other entities for the health management of pregnant women and children described in subparagraph (A).

(2) **REQUIRED ACTIVITIES.**—The Secretary may make a grant under paragraph (1) only if the applicant involved agrees to expend the grant for the following activities with respect to the purpose described in such paragraph:

(A) Primary health services, including prenatal care.

(B) Community education, outreach, and case finding.

(C) Case management services.

(D) Client education, including parenting and child development education.

(3) CERTAIN AUTHORIZED ACTIVITIES.—The purposes for which a grant under paragraph (1) may be expended include, with respect to the purpose described in such paragraph, substance abuse screening, counseling and referral services, and other necessary nonmedical support services, including child care, translation services, and housing assistance.

(4) CERTAIN REQUIREMENTS REGARDING PROVISION OF SERVICES.—The Secretary may make a grant under paragraph (1) only if the applicant involved agrees that—

(A) the applicant will coordinate the provision of services under the grant to each of the recipients of the services;

(B) such services will be continuous for each such recipient;

(C) the applicant will provide follow-up services for individuals who are referred by the applicant for services described in paragraph (3); and

(D) the grant will be expended to supplement, and not supplant, the expenditures of the applicant for primary health services (including prenatal care) with respect to the purpose described in paragraph (1).

(5) APPLICATION FOR GRANT.—The Secretary may make a grant under paragraph (1) only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this subsection.

(6) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1993 and 1994.

Subpart VI—Health Services for Residents of Public Housing

HEALTH SERVICES FOR RESIDENTS OF PUBLIC HOUSING

SEC. 340A. [256a] (a) ESTABLISHMENT.—

(1) The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make grants for the purpose of enabling grantees, directly or through contracts, to provide to residents of public housing, subject to subsections (e) and (f)—

(A) primary health services, including health screenings; and

(B) health counseling and education services.

(2) The Secretary may not make a grant under paragraph (1) unless the applicant for the grant agrees to expend the grant to carry out each of subparagraphs (A) and (B) of such paragraph.

(3) In carrying out the program established in paragraph (1), the Administrator shall consult with the Director of the Centers for Disease Control.

(b) MINIMUM QUALIFICATIONS OF GRANTEES.—

(1) Subject to paragraph (2), the Secretary may not make a grant under subsection (a) to an applicant unless—

(A) the applicant is a public or nonprofit private entity;

(B) the applicant has the capacity to effectively administer a grant under subsection (a); and

(C) in the case of any service under this section that is available pursuant to the State plan approved under title XIX of the Social Security Act for the State in which the service will be provided—

(i) the applicant for the grant will provide the service directly, and the applicant has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the applicant for the grant will enter into an agreement with a public or nonprofit private organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(2)(A) In the case of an organization making an agreement pursuant to paragraph (1)(C)(ii) regarding the provision of services under subsection (a), the requirement established in such paragraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(B) A determination by the Secretary of whether an organization referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(c) PREFERENCES IN MAKING GRANTS.—The Secretary shall, in making grants under subsection (a), give preference to qualified applicants that—

(1) are resident management corporations under section 20 of the United States Housing Act of 1937; or

(2) are receiving funds under section 330 or 340.

(d) REQUIREMENT OF MATCHING FUNDS FROM PUBLIC GRANTEES.—

(1) In the case of a public entity applying for a grant under subsection (a), the Secretary may not make such a grant unless the public entity agrees that, with respect to the costs to be incurred by such entity in carrying out the purpose described in such subsection, the entity will make available non-Federal contributions in cash toward such costs in an amount equal to not less than \$1 for each \$1 of Federal funds provided in the grant.

(2) In determining the amount of non-Federal contributions in cash that a public entity has provided pursuant to paragraph (1), the Secretary may not include any amounts provided to the public entity by the Federal Government.

(e) REQUIREMENTS REGARDING SERVICES.—The Secretary may not make a grant under subsection (a) to an applicant unless the applicant agrees that the applicant will, directly or through contract—

(1) provide services under this section on the premises of public housing projects or at other locations immediately accessible to residents of public housing;

(2) refer such residents, as appropriate, to qualified facilities and practitioners for necessary follow-up services;

(3) provide outreach services to inform such residents of the availability of such services; and

(4) aid such residents in establishing eligibility for assistance, and in obtaining services, under Federal, State, and local programs providing health services, mental health services, or social services.

(f) OPTIONAL PROVISION OF CERTAIN SERVICES.—

(1) A grantee under subsection (a) may expend the grant—

(A) to train residents of public housing to provide health screenings and to provide educational services; and

(B) to provide health services to individuals who are not residents of public housing.

(2) The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that if, pursuant to paragraph (1)(B), the applicant provides health services to individuals who are not residents of public housing, the health services will be provided to such individuals under the same terms and conditions as such services are provided to residents of public housing (including all terms and conditions in effect pursuant to this section).

(g) CONSULTATION WITH RESIDENTS.—The Secretary may not make a grant under subsection (a) unless, with respect to the residents of the public housing involved, the applicant for the grant—

(1) has consulted with the residents in the preparation of the application for the grant; and

(2) agrees to provide for ongoing consultation with the residents regarding the planning and administration of the program carried out with the grant.

(h) RESTRICTIONS ON USE OF GRANT FUNDS.—

(1) The Secretary may not, except as provided in paragraph (2), make a grant under subsection (a) to an applicant unless the applicant agrees that amounts received pursuant to such subsection will not, directly or through contract, be expended—

(A) for any purpose other than the purposes authorized in this section;

(B) to provide inpatient services;

(C) to make cash payments to intended recipients of services under this section; or

(D) to purchase or improve real property (other than minor remodeling of existing improvements to real property) or to purchase major medical equipment or motor vehicles.

(2) If the Secretary finds that the purpose described in subsection (a) cannot otherwise be carried out, the Secretary

may, with respect to an otherwise qualified applicant, waive the restriction established in paragraph (1)(D).

(i) **LIMITATION ON CHARGES FOR SERVICES.**—The Secretary may not make a grant under subsection (a) to an applicant unless the applicant agrees that, whether the services are provided directly or through contract—

(1) services under the grant will be provided without regard to ability to pay for the services; and

(2) if a charge is imposed for the delivery of the services, such charge—

(A) will be made according to a schedule of charges that is made available to the public;

(B) will not be imposed on any resident of public housing with an income less than the official poverty level; and

(C) will be adjusted to reflect the income and resources of the resident of public housing involved.

(j) **REQUIREMENTS REGARDING ADMINISTRATION.**—The Secretary may not make a grant under subsection (a) to an applicant unless the applicant—

(1) agrees to establish such procedures for fiscal control and fund accounting as may be necessary to ensure proper disbursement and accounting with respect to the grant;

(2) agrees to establish an ongoing program of quality assurance with respect to the services provided under the grant;

(3) agrees to ensure the confidentiality of records maintained on residents of public housing that are receiving such services;

(4) with respect to providing services to any population of such residents a substantial portion of which has a limited ability to speak the English language—

(A) has developed and has the ability to carry out a reasonable plan to provide services under the grant through individuals who are able to communicate with the population involved in the language and cultural context that is most appropriate; and

(B) has designated at least one individual, fluent in both English and the appropriate language, to assist in carrying out the plan; and

(5) agrees to submit to the Secretary an annual report that describes the utilization and costs of services provided under the grant and that provides such other information as the Secretary determines to be appropriate.

(k) **LIMITATION ON ADMINISTRATIVE EXPENSES OF GRANTEE.**—The Secretary may not make a grant under subsection (a) to an applicant unless the applicant agrees that the applicant will not expend more than 10 percent of amounts received pursuant to such subsection for the purpose of administering the grant.

(l) **REQUIREMENT OF APPLICATION.**—The Secretary may not provide financial assistance under subsection (a) unless—

(1) an application for the assistance is submitted to the Secretary;

(2) with respect to carrying out the purpose for which the assistance is to be provided, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(m) TECHNICAL ASSISTANCE.—

(1) The Secretary may provide technical assistance to applicants and grantees under subsection (a) regarding the planning, development, and operation of programs to carry out the purpose described in such subsection. The Secretary may provide such technical assistance directly, through contracts, or through grants.

(2) Any technical assistance provided by the Secretary under paragraph (1) shall be provided without charge to applicants and grantees under subsection (a).

(3) Of the amounts appropriated pursuant to subsection (p)(1) for a fiscal year, the Secretary may expend not more than \$2,000,000 for the purpose of carrying out paragraph (1).

(n) ANNUAL REPORTS BY SECRETARY.—Not later than January 10 of each year, the Secretary shall submit to the Congress a report describing the utilization and costs of services provided under this section during the immediately preceding fiscal year.

(o) DEFINITIONS.—For purposes of this section:

(1) The term “official poverty level” means the nonfarm income official poverty line defined by the Office of Management and Budget and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(2) The term “organization” includes individuals, corporations, partnerships, companies, and associations.

(3) The term “primary health services” has the meaning given such term in section 330(b)(1).

(4) The term “public housing” has the meaning given such term in section 3(b)(1) of the United States Housing Act of 1937.

(p) FUNDING.—

(1) For the purpose of carrying out this section, there are authorized to be appropriated \$35,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

(2) Amounts received by a grantee pursuant to subsection (a) remaining unobligated at the end of the fiscal year in which the amounts were received shall remain available to the grantee during the succeeding fiscal year for the purpose described in such subsection.

(q) INFANT MORTALITY AND MORBIDITY.—

(1) IN GENERAL.—The Secretary may make grants to grantees under subsection (a) for the purpose of assisting such grantees in—

(A) providing comprehensive health care and support services for the reduction of (i) the incidence of infant mortality, and (ii) morbidity among children who are less than 3 years of age; and

(B) developing and coordinating service and referral arrangements between such grantees and other entities for

the health management of pregnant women and children described in subparagraph (A).

(2) REQUIRED ACTIVITIES.—The Secretary may make a grant under paragraph (1) only if the applicant involved agrees to expend the grant for the following activities with respect to the purpose described in such paragraph:

(A) Primary health services, including prenatal care.

(B) Community education, outreach, and case finding.

(C) Case management services.

(D) Client education, including parenting and child development education.

(3) CERTAIN AUTHORIZED ACTIVITIES.—The purposes for which a grant under paragraph (1) may be expended include, with respect to the purpose described in such paragraph, substance abuse screening, counseling and referral services, and other necessary nonmedical support services, including child care, translation services, and housing assistance.

(4) CERTAIN REQUIREMENTS REGARDING PROVISION OF SERVICES.—The Secretary may make a grant under paragraph (1) only if the applicant involved agrees that—

(A) the applicant will coordinate the provision of services under the grant to each of the recipients of the services;

(B) such services will be continuous for each such recipient;

(C) the applicant will provide follow-up services for individuals who are referred by the applicant for services described in paragraph (3); and

(D) the grant will be expended to supplement, and not supplant, the expenditures of the applicant for primary health services (including prenatal care) with respect to the purpose described in paragraph (1).

(5) APPLICATION FOR GRANT.—The Secretary may make a grant under paragraph (1) only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this subsection.

(6) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1993 and 1994.

Subpart VII—Drug Pricing Agreements

LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES

SEC. 340B. [256b] (a) REQUIREMENTS FOR AGREEMENT WITH SECRETARY.—

(1) IN GENERAL.—The Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the

first month that begins after the date of the enactment of this section, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

(2) REBATE PERCENTAGE DEFINED.—

(A) IN GENERAL.—For a covered outpatient drug purchased in a calendar quarter, the “rebate percentage” is the amount (expressed as a percentage) equal to—

(i) the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) OVER THE COUNTER DRUGS.—

(i) IN GENERAL.—For purposes of subparagraph (A), in the case of over the counter drugs, the “rebate percentage” shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(4) of such Act.

(ii) DEFINITION.—The term “over the counter drug” means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) DRUGS PROVIDED UNDER STATE MEDICAID PLANS.—Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act.

(4) COVERED ENTITY DEFINED.—In this section, the term “covered entity” means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).

(B) An entity receiving a grant under section 340A.

(C) A family planning project receiving a grant or contract under section 1001.

(D) An entity receiving a grant under subpart II of part C of title XXVI (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI.

(F) A black lung clinic receiving funds under section 427(a) of the Black Lung Benefits Act.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(J) Any entity receiving assistance under title XXVI (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 318 (relating to treatment of sexually transmitted diseases) or section 317(j)(2) (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(5) REQUIREMENTS FOR COVERED ENTITIES.—

(A) PROHIBITING DUPLICATE DISCOUNTS OR REBATES.—

(i) IN GENERAL.—A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) ESTABLISHMENT OF MECHANISM.—The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) PROHIBITING RESALE OF DRUGS.—With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) AUDITING.—A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

(D) ADDITIONAL SANCTION FOR NONCOMPLIANCE.—If the Secretary finds, after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) TREATMENT OF DISTINCT UNITS OF HOSPITALS.—In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) CERTIFICATION OF CERTAIN COVERED ENTITIES.—

(A) DEVELOPMENT OF PROCESS.—Not later than 60 days after the date of enactment of this subsection, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) INCLUSION OF PURCHASE INFORMATION.—The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) CRITERIA.—The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) LIST OF PURCHASERS AND DISPENSERS.—The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) RECERTIFICATION.—The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of

subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) DEVELOPMENT OF PRIME VENDOR PROGRAM.—The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) NOTICE TO MANUFACTURERS.—The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) NO PROHIBITION ON LARGER DISCOUNT.—Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) OTHER DEFINITIONS.—In this section, the terms “average manufacturer price”, “covered outpatient drug”, and “manufacturer” have the meaning given such terms in section 1927(k) of the Social Security Act.

(c) REFERENCES TO SOCIAL SECURITY ACT.—Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of the enactment of this section.

(d) COMPLIANCE WITH REQUIREMENTS.—A manufacturer is deemed to meet the requirements of subsection (a) if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of this section (as in effect immediately after the enactment of the Veterans Health Care Act of 1992), as applied by the Secretary, and would have entered into an agreement under this section (as such section was in effect at such time), but for a legislative change in this section (or the application of this section) after the date of the enactment of such Act.

Subpart VIII—Bulk Purchases of Vaccines for Certain Programs

BULK PURCHASES OF VACCINES FOR CERTAIN PROGRAMS

SEC. 340C. [256c] (a) AGREEMENTS FOR PURCHASES.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of the Preventive Health Amendments of 1992¹, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator of the Health Resources and Services Administration, shall enter into negotiations with manufacturers of vaccines for the purpose of establishing and maintaining agreements under which entities described in paragraph (2) may purchase vaccines from the manufacturers at the prices specified in the agreements.

¹Enacted October 27, 1992.

(2) **RELEVANT ENTITIES.**—The entities referred to in paragraph (1) are entities that provide immunizations against vaccine-preventable diseases under the programs established in sections 329, 330, 340, and 340A.

(b) **NEGOTIATION OF PRICES.**—In carrying out subsection (a), the Secretary shall, to the extent practicable, ensure that the prices provided for in agreements under such subsection are comparable to the prices provided for in agreements negotiated by the Secretary on behalf of grantees under section 317(j)(1).

(c) **AUTHORITY OF SECRETARY.**—In carrying out subsection (a), the Secretary, in the discretion of the Secretary, may enter into the agreements described in such subsection (and may decline to enter into such agreements), may modify such agreements, may extend such agreements, and may terminate such agreements.

(d) **RULE OF CONSTRUCTION.**—This section may not be construed as requiring any State to reduce or terminate the supply of vaccines provided by the State to any of the entities described in subsection (a)(2).

BREAST AND CERVICAL CANCER INFORMATION

SEC. 340D. [256d] (a) **IN GENERAL.**—As a condition of receiving grants, cooperative agreements, or contracts under this Act, each of the entities specified in subsection (c) shall, to the extent determined to be appropriate by the Secretary, make available information concerning breast and cervical cancer.

(b) **CERTAIN AUTHORITIES.**—In carrying out subsection (a), an entity specified in subsection (c)—

(1) may make the information involved available to such individuals as the entity determines appropriate;

(2) may, as appropriate, provide information under subsection (a) on the need for self-examination of the breasts and on the skills for such self-examinations;

(3) shall provide information under subsection (a) in the language and cultural context most appropriate to the individuals to whom the information is provided; and

(4) shall refer such clients as the entities determine appropriate for breast and cervical cancer screening, treatment, or other appropriate services.

(c) **RELEVANT ENTITIES.**—The entities specified in this subsection are the following:

(1) Entities receiving assistance under section 317E (relating to tuberculosis).

(2) Entities receiving assistance under section 318 (relating to sexually transmitted diseases).

(3) Migrant health centers receiving assistance under section 329.

(4) Community health centers receiving assistance under section 330.

(5) Entities receiving assistance under section 340 (relating to homeless individuals).

(6) Entities receiving assistance under section 340A (relating to health services for residents of public housing).

(7) Entities providing services with assistance under title V or title XIX.

(8) Entities receiving assistance under section 1001 (relating to family planning).

(9) Entities receiving assistance under title XXVI (relating to services with respect to acquired immune deficiency syndrome).

(10) Non-Federal entities authorized under the Indian Self-Determination Act.

PART E—NARCOTIC ADDICTS AND OTHER DRUG ABUSERS

CARE AND TREATMENT

SEC. 341. [257] (a) The Surgeon General is authorized to provide for the confinement, care, protection, treatment, and discipline of persons addicted to the use of habit-forming narcotic drugs who are civilly committed to treatment under the Narcotic Addict Rehabilitation Act of 1966, addicts and other persons with drug abuse and drug dependence problems who voluntarily submit themselves for treatment, and addicts convicted of offenses against the United States, including persons convicted by general courts-martial and consular courts. Such care and treatment shall be provided at hospitals of the Service especially equipped for the accommodation of such patients or elsewhere where authorized under other provisions of law, and shall be designed to rehabilitate such persons, to restore them to health, and, where necessary, to train them to be self-supporting and self-reliant; but nothing in this section or in this part shall be construed to limit the authority of the Surgeon General under other provisions of law to provide for the conditional release of patients and for aftercare under supervision. In carrying out this subsection, the Secretary shall establish in each hospital and other appropriate medical facility of the Service a treatment and rehabilitation program for drug addicts and other persons with drug abuse and drug dependence problems who are in the area served by such hospital or other facility; except that the requirement of this sentence shall not apply in the case of any such hospital or other facility with respect to which the Secretary determines that there is not sufficient need for such a program in such hospital or other facility.

(b) Upon the admittance to, and departure from, a hospital of the Service of a person who voluntarily submitted himself for treatment pursuant to the provisions of this section, and who at the time of his admittance to such hospital was a resident of the District of Columbia, the Surgeon General shall furnish to the Commissioners of the District of Columbia or their designated agent, the name, address, and such other pertinent information as may be useful in the rehabilitation to society of such person.

(c) The Secretary may enter into agreements with the Secretary of Veterans Affairs, the Secretary of Defense, and the head of any other department or agency of the Government under which agreements hospitals and other appropriate medical facilities of the Service may be used in treatment and rehabilitation programs provided by such department or agency for drug addicts and other persons with drug abuse and other drug dependence problems who are in areas served by such hospitals or other facilities.

EMPLOYMENT OF ADDICTS OR OTHER PERSONS WITH DRUG ABUSE AND DRUG DEPENDENCE PROBLEMS

SEC. 342. [258] Narcotic addicts or other persons with drug abuse and drug dependence problems in hospitals of the Service designated for their care shall be employed in such manner and under such conditions as the Surgeon General may direct. In such hospitals the Surgeon General may, in his discretion, establish industries, plants, factories, or shops for the production and manufacture of articles, commodities, and supplies for the United States Government. The Secretary of the Treasury may require any Government department, establishment, or other institution, for whom appropriations are made directly or indirectly by the Congress of the United States, to purchase at current market prices, as determined by him or his authorized representative, such of the articles, commodities, or supplies so produced or manufactured as meet their specifications; and the Surgeon General shall provide for payment to the inmates or their dependents of such pecuniary earnings as he may deem proper. The Secretary shall establish a working-capital fund for such industries, plants, factories, and shops out of any funds appropriated for Public Health Service hospitals at which addicts or other persons with drug abuse and drug dependence problems are treated and cared for; and such fund shall be available for the purchase, repair, or replacement of machinery or equipment, for the purchase of raw materials and supplies, for the purchase of uniforms and other distinctive wearing apparel of employees in the performance of their official duties, and for the employment of necessary civilian officers and employees. The Surgeon General may provide for the disposal of products of the industrial activities conducted pursuant to this section, and the proceeds of any sales thereof shall be covered into the Treasury of the United States to the credit of the working-capital fund.

CONVICTS

SEC. 343. [259] (a) The authority vested with the power to designate the place of confinement of a prisoner shall transfer to hospitals of the Service especially equipped for the accommodation of addicts or other persons with drug abuse and drug dependence problems, if accommodations are available, all addicts or other persons with drug abuse and drug dependence problems who have been or are hereafter sentenced to confinement, or who are now or shall hereafter be confined, in any penal, correctional, disciplinary, or reformatory institution of the United States, including those addicts or other persons with drug abuse and drug dependence problems convicted of offenses against the United States who are confined in State and Territorial prisons, penitentiaries, and reformatories, except that no addict or other person with a drug abuse or other drug dependence problem shall be transferred to a hospital of the Service who, in the opinion of the officer authorized to direct the transfer, is not a proper subject for confinement in such an institution either because of the nature of the crime he has committed or because of his apparent incorrigibility. The authority vested with the power to designate the place of confinement of a prisoner shall transfer from a hospital of the Service to the institution from

which he was received, or to such other institution as may be designated by the proper authority, any addict or other person with a drug abuse or other drug dependence problem whose presence at a hospital of the Service is detrimental to the well-being of the hospital or who does not continue to be a narcotic addict or other person with a drug abuse or other drug dependence problem. All transfers of such prisoners to or from a hospital of the Service shall be accompanied by necessary attendants as directed by the officer in charge of such hospital and the actual and necessary expenses incident to such transfers shall be paid from the appropriation for the maintenance of such Service hospital except to the extent that other Federal agencies are authorized or required by law to pay expenses incident to such transfers. When sentence is pronounced against any person whom the prosecuting officer believes to be an addict or other person with a drug abuse or other drug dependence problem such officer shall report to the authority vested with the power to designate the place of confinement, the name of such person, the reasons for his belief, all pertinent facts bearing on such addiction, drug abuse, or drug dependence and the nature of the offense committed. Whenever an alien addict or other person with a drug abuse or other drug dependence problem transferred to a Service hospital pursuant to this subsection is entitled to his discharge but is subject to deportation, in lieu of being returned to the penal institution from which he came he shall be deported by the authority vested by law with power over deportation.

(b) [Repealed.]

(c) Not later than one month prior to the expiration of the sentence of any addict or other person with a drug abuse or other drug dependence problem confined in a Service hospital, he shall be examined by the Surgeon General or his authorized representative. If the Surgeon General believes the person to be discharged is still an addict or other person with a drug abuse or other drug dependence problem and that he may by further treatment in a Service hospital be cured of his addiction, drug abuse, or drug dependence the addict or other person with a drug abuse or other drug dependence problem shall be informed, in accordance with regulations, of the advisability of his submitting himself to further treatment. The addict or other person with a drug abuse or other drug dependence problem may then apply in writing to the Surgeon General for further treatment in a Service hospital for a period not exceeding the maximum length of time considered necessary by the Surgeon General. Upon approval of the application by the Surgeon General or his authorized agent, the addict or other person with a drug abuse or other drug dependence problem may be given such further treatment as is necessary to cure him of his addiction, drug abuse, or drug dependence.

(d) Every person convicted of an offense against the United States, upon discharge, or upon release on parole or supervised release from a hospital of the Service, shall be furnished with the gratuities and transportation authorized by law to be furnished to prisoners upon release from a penal, correctional, disciplinary, or reformatory institution.

(e) Any court of the United States having the power to suspend the imposition or execution of sentence and to place a defendant on

probation under any existing laws may impose as one of the conditions of such probation that the defendant, if an addict, or other person with a drug abuse or other drug dependence problem shall submit himself for treatment at a hospital of the Service especially equipped for the accommodation of addicts or other persons with drug abuse and drug dependence problems until discharged therefrom as cured and that he shall be admitted thereto for such purpose. Upon the discharge of any such probationer from a hospital of the Service, he shall be furnished with the gratuities and transportation authorized by law to be furnished to prisoners upon release from a penal, correctional, disciplinary, or reformatory institution. The actual and necessary expense incident to transporting such probationer to such hospital and to furnishing such transportation and gratuities shall be paid from the appropriation for the maintenance of such hospital except to the extent that other Federal agencies are authorized or required by law to pay the cost of such transportation: *Provided*, That where existing law vests a discretion in any officer as to the place to which transportation shall be furnished or as to the amount of clothing and gratuities to be furnished, such discretion shall be exercised by the Surgeon General with respect to addicts or other persons with drug abuse and drug dependence problems discharged from hospitals of the Service.

VOLUNTARY PATIENTS

SEC. 344. [260] (a) Any addict, or other person with a drug abuse or other drug dependence problem whether or not he shall have been convicted of an offense against the United States, may apply to the Surgeon General for admission to a hospital of the Service especially equipped for the accommodation of addicts or other persons with drug abuse and drug dependence problems.

(b) Any applicant shall be examined by the Surgeon General who shall determine whether the applicant is an addict, or other person with a drug abuse or other drug dependence problem whether by treatment in a hospital of the Service he may probably be cured of his addiction, drug abuse, or drug dependence and the estimated length of time necessary to effect his cure. The Surgeon General may, in his discretion, admit the applicant to a Service hospital. No such addict or other person with drug abuse or other drug dependence problem shall be admitted unless he agrees to submit to treatment for the maximum amount of time estimated by the Surgeon General to be necessary to effect a cure, and unless suitable accommodations are available after all eligible addicts or other persons with drug abuse and drug dependence problems convicted of offenses against the United States have been admitted. Any such addict or other person with a drug abuse or other drug dependence problem may be required to pay for his subsistence, care, and treatment at rates fixed by the Surgeon General and amounts so paid shall be covered into the Treasury of the United States to the credit of the appropriation from which the expenditure for his subsistence, care, and treatment was made. Appropriations available for the care and treatment of addicts or other persons with drug abuse and drug dependence problems admitted to a hospital of the Service under this section shall be available, subject to regulations, for paying the cost of transportation to any

place within the continental United States, including subsistence allowance while traveling, for any indigent addict or other person with a drug abuse or other drug dependence problem who is discharged as cured.

(c) Any addict or other person with a drug abuse or other drug dependence problem admitted for treatment under this section, including any addict, or other person with a drug abuse or other drug dependence problem not convicted of an offense, who voluntarily submits himself for treatment, may be confined in a hospital of the Service for a period not exceeding the maximum amount of time estimated by the Surgeon General as necessary to effect a cure of the addiction, drug abuse, or drug dependence or until such time as he ceases to be an addict or other person with a drug abuse or other drug dependence problem.

(d) Any addict or other person with a drug abuse or other drug dependence problem admitted for treatment under this section shall not thereby forfeit or abridge any of his rights as a citizen of the United States; nor shall such admission or treatment be used against him in any proceeding in any court; and the record of his voluntary commitment shall, except as otherwise provided by this Act, be confidential and shall not be divulged.

PERSONS COMMITTED FROM DISTRICT OF COLUMBIA

SEC. 345. [260a] (a) The Surgeon General is authorized to admit for care and treatment in any hospital of the Service suitably equipped therefor, and thereafter to transfer between hospitals of the Service in accordance with section 321(b), any addict who is committed, under the provisions of the Act of June 24, 1953 (Public Law 76, Eighty-third Congress¹, to the Service or to a hospital thereof for care and treatment and who the Surgeon General determines is a proper subject for care and treatment. No such addict shall be admitted unless (1) committed prior to July 1, 1958; and (2) at the time of commitment, the number of persons in hospitals of the Service who have been admitted pursuant to this subsection is less than 100; and (3) suitable accommodations are available after all eligible addicts convicted of offenses against the United States have been admitted.

(b) Any person admitted to a hospital of the Service pursuant to subsection (a) shall be discharged therefrom (1) upon order of the Superior Court of the District of Columbia, or (2) when he is found by the Surgeon General to be cured and rehabilitated. When any such person is so discharged, the Surgeon General shall give notice thereof to the Superior Court of the District of Columbia and shall deliver such person to such court for such further action as such court may deem necessary and proper under the provisions of the Act of June 24, 1953 (Public Law 76, Eighty-third Congress).¹

(c) With respect to the detention, transfer, parole, or discharge of any person committed to a hospital of the Service in accordance with subsection (a), the Surgeon General and the officer in charge of the hospital, in addition to authority otherwise vested in them, shall have such authority as may be conferred upon them, respectively, by the order of the committing court.

¹67 Stat. 77. Codified to section 24-601 et seq., D.C. Code.

(d) The cost of providing care and treatment for persons admitted to a hospital of the Service pursuant to subsection (a) shall be a charge upon the District of Columbia and shall be paid by the District of Columbia to the Public Health Service, either in advance or otherwise, as may be determined by the Surgeon General. Such cost may be determined for each addict or on the basis of rates established for all or particular classes of patients, and shall include the cost of transportation to and from facilities of the Public Health Service. Moneys so paid to the Public Health Service shall be covered into the Treasury of the United States as miscellaneous receipts. Appropriations available for the care and treatment of addicts admitted to a hospital of the Service under this section shall be available, subject to regulations, for paying the cost of transportation to the District of Columbia, including subsistence allowance while traveling, for any such addict who is discharged.

PENALTIES

SEC. 346. [261] (a) Any person not authorized by law or by the Surgeon General who introduces or attempts to introduce into or upon the grounds of any hospital of the Service at which addicts or other persons with drug abuse and drug dependence problems are treated and cared for, any habit-forming narcotic drug, or substance controlled under the Controlled Substances Act, weapon, or any other contraband article or thing, or any contraband letter or message intended to be received by an inmate thereof, shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not more than ten years.

(b) It shall be unlawful for any person properly committed thereto to escape or attempt to escape from a hospital of the Service at which addicts or other persons with drug abuse and drug dependence problems are treated and cared for, and any such person upon apprehension and conviction in a United States court shall be punished by imprisonment for not more than five years, such sentence to begin upon the expiration of the sentence for which such person was originally confined.

(c) Any person who procures the escape of any person admitted to a hospital of the Service at which addicts or other persons with drug abuse and drug dependence problems are treated and cared for, or who advises, connives at, aids, or assists in such escape, or who conceals any such inmate after such escape, shall be punished upon conviction in a United States court by imprisonment in the penitentiary for not more than three years.

RELEASE OF PATIENTS

SEC. 347. [261a] For purposes of this Act, an individual shall be deemed cured of his addiction, drug abuse, or drug dependence, and rehabilitated if the Surgeon General determines that he has received the maximum benefits of treatment and care by the Service for his addiction, drug abuse, or drug dependence, or if the Surgeon General determines that his further treatment and care for such purpose would be detrimental to the interests of the Service.

PART F—LICENSING—BIOLOGICAL PRODUCTS AND CLINICAL
LABORATORIES

Subpart 1—Biological Products

REGULATION OF BIOLOGICAL PRODUCTS

SEC. 351. [262] (a) No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; and (2) each package of such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product is plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results. The suspension or revocation of any license shall not prevent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid which has been sold and delivered by the licensee prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid has been notified by the Secretary not to sell, barter, or exchange the same.

(b) No person shall falsely label or mark any package or container or any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid so as to falsify such label or mark.

(c) Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State

or possession or into any foreign country, or from any foreign country into any State or possession.

(d)(1) Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishment for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.

(2)(A) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5, United States Code.

(B) Any violation of subparagraph (A) shall subject the violator to a civil penalty of up to \$100,000 per day of violation. The amount of a civil penalty under this subparagraph shall, effective December 1 of each year beginning 1 year after the effective date of this subparagraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest $\frac{1}{10}$ of 1 percent. For purposes of this subparagraph, the term "base quarter", as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding \$500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act (U.S.C., 1940 edition, title 21, ch. 9).¹

(h)(1)(A) A partially processed biological product which is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man, which is not intended for sale in the United States, and which is intended for further manufacture into final

¹ Codification remains chapter 9 of title 21, United States Code (§321 et seq.).

dosage form outside the United States in a country listed under section 802(b)(A)¹ of the Federal Food, Drug, and Cosmetic Act may, upon approval of an application meeting the requirements of subparagraph (B), be exported to a country listed under section 802(b)(4) of the Federal Food, Drug, and Cosmetic Act. The Secretary may not approve an application to export such a product unless the Secretary determines that the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice and the outside of the shipping package is labeled with the following statement: "This product may be sold or offered for sale only in the following countries: ", the blank space being filled with a list of the countries to which export of the drug is authorized.

(B) An application for the export of a partially processed biological product shall—

(i) describe the partially processed biological product to be exported,

(ii) list each country to which the product is to be exported,

(iii) contain a certification by the applicant that the product will not be exported to a country not listed under clause (ii),

(iv) identify the establishments in which the product is manufactured, and

(v) contain a certification by the applicant that the final product to be developed from the partially processed product is approved in the country to which it is to be exported or approval of the final product is being sought in such country.

(2) A product described in paragraph (1) is not subject to licensure under this section.

(3) If the Secretary determines that prohibiting the export of a product described in paragraph (1) is necessary for protection of the public health in the United States or the country to which it is to be exported, the Secretary may not approve an application under paragraph (1) for the export of such product.

PREPARATION OF BIOLOGICAL PRODUCTS

SEC. 352. [263] (a) The Service may prepare for its own use any product described in section 351 and any product necessary to carrying out any of the purposes of section 301.

(b) The Service may prepare any product described in section 351 for the use of other Federal departments or agencies, and public or private agencies and individuals engaged in work in the field of medicine when such product is not available from establishments licensed under such section.

Subpart 2—Clinical Laboratories

CERTIFICATION OF LABORATORIES

SEC. 353. [263a] (a) DEFINITION.—As used in this section, the term "laboratory" or "clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological,

¹ So in original. Probably should be "802(b)(4)(A)".

or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(b) **CERTIFICATE REQUIREMENT.**—No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

(c) **ISSUANCE AND RENEWAL OF CERTIFICATES.**—

(1) **IN GENERAL.**—The Secretary may issue or renew a certificate for a laboratory only if the laboratory meets the requirements of subsection (d).

(2) **TERM.**—A certificate issued under this section shall be valid for a period of 2 years or such shorter period as the Secretary may establish.

(d) **REQUIREMENTS FOR CERTIFICATES.**—

(1) **IN GENERAL.**—A laboratory may be issued a certificate or have its certificate renewed if—

(A) the laboratory submits (or if the laboratory is accredited under subsection (e), the accreditation body which accredited the laboratory submits), an application—

(i) in such form and manner as the Secretary shall prescribe,

(ii) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory including—

(I) the number and types of laboratory examinations and other procedures performed,

(II) the methodologies for laboratory examinations and other procedures employed, and

(III) the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and

(iii) that contains such other information as the Secretary may require to determine compliance with this section, and

the laboratory agrees to provide to the Secretary (or if the laboratory is accredited, to the accreditation body which accredited it) a description of any change in the information submitted under clause (ii) not later than 6 months after the change was put into effect,

(B) the laboratory provides the Secretary—

(i) with satisfactory assurances that the laboratory will be operated in accordance with standards issued by the Secretary under subsection (f), or

(ii) with proof of accreditation under subsection (e),

(C) the laboratory agrees to permit inspections by the Secretary under subsection (g),

(D) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may reasonably require, and

(E) the laboratory agrees to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business.

(2) REQUIREMENTS FOR CERTIFICATES OF WAIVER.—

(A) IN GENERAL.—A laboratory which only performs laboratory examinations and procedures described in paragraph (3) shall be issued a certificate of waiver or have its certificate of waiver renewed if—

(i) the laboratory submits an application—

(I) in such form and manner as the Secretary shall prescribe,

(II) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory, including the number and types of laboratory examinations and other procedures performed, the methodologies for laboratory examinations and other procedures employed, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and

(III) that contains such other information as the Secretary may reasonably require to determine compliance with this section, and

(ii) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may require.

(B) CHANGES.—If a laboratory makes changes in the examinations and other procedures performed by it only with respect to examinations and procedures which are described in paragraph (3), the laboratory shall report such changes to the Secretary not later than 6 months after the change has been put into effect. If a laboratory proposes to make changes in the examinations and procedures performed by it such that the laboratory will perform an examination or procedure not described in paragraph (3), the laboratory shall report such change to the Secretary before the change takes effect.

(C) EFFECT.—Subsections (f) and (g) shall not apply to a laboratory to which has been issued a certificate of waiver.

(3) EXAMINATIONS AND PROCEDURES.—The examinations and procedures identified in paragraph (2) are simple laboratory examinations and procedures which, as determined by the Secretary, have an insignificant risk of an erroneous result, including those which—

(A) have been approved by the Food and Drug Administration for home use,

(B) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or

(C) the Secretary has determined pose no reasonable risk of harm to the patient if performed incorrectly.

(4) DEFINITION.—As used in this section, the term “certificate” includes a certificate of waiver issued under paragraph (2).

(e) ACCREDITATION.—

(1) IN GENERAL.—A laboratory may be accredited for purposes of obtaining a certificate if the laboratory—

(A) meets the standards of an approved accreditation body, and

(B) authorizes the accreditation body to submit to the Secretary (or such State agency as the Secretary may designate) such records or other information as the Secretary may require.

(2) APPROVAL OF ACCREDITATION BODIES.—

(A) IN GENERAL.—The Secretary may approve a private nonprofit organization to be an accreditation body for the accreditation of laboratories if—

(i) using inspectors qualified to evaluate the methodologies used by the laboratories in performing laboratory examinations and other procedures, the accreditation body agrees to inspect a laboratory for purposes of accreditation with such frequency as determined by Secretary,¹

(ii) the standards applied by the body in determining whether or not to accredit a laboratory are equal to or more stringent than the standards issued by the Secretary under subsection (f),

(iii) there is adequate provision for assuring that the standards of the accreditation body continue to be met by the laboratory,

(iv) in the case of any laboratory accredited by the body which has had its accreditation denied, suspended, withdrawn, or revoked or which has had any other action taken against it by the accrediting body, the accrediting body agrees to submit to the Secretary the name of such laboratory within 30 days of the action taken,

(v) the accreditation body agrees to notify the Secretary at least 30 days before it changes its standards, and

(vi) if the accreditation body has its approval withdrawn by the Secretary, the body agrees to notify each laboratory accredited by the body of the withdrawal within 10 days of the withdrawal.

(B) CRITERIA AND PROCEDURES.—The Secretary shall promulgate criteria and procedures for approving an accreditation body and for withdrawing such approval if the

¹ So in original. Probably should be “the Secretary”.

Secretary determines that the accreditation body does not meet the requirements of subparagraph (A).

(C) EFFECT OF WITHDRAWAL OF APPROVAL.—If the Secretary withdraws the approval of an accreditation body under subparagraph (B), the certificate of any laboratory accredited by the body shall continue in effect for 60 days after the laboratory receives notification of the withdrawal of the approval, except that the Secretary may extend such period for a laboratory if it¹ determines that the laboratory submitted an application for accreditation or a certificate in a timely manner after receipt of the notification of the withdrawal of approval. If an accreditation body withdraws or revokes the accreditation of a laboratory, the certificate of the laboratory shall continue in effect—

- (i) for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or
- (ii) until the effective date of any action taken by the Secretary under subsection (i).

(D) EVALUATIONS.—The Secretary shall evaluate annually the performance of each approved accreditation body by—

- (i) inspecting under subsection (g) a sufficient number of the laboratories accredited by such body to allow a reasonable estimate of the performance of such body, and
- (ii) such other means as the Secretary determines appropriate.

(3) REPORT.—The Secretary shall annually prepare and submit, to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report that describes the results of the evaluation conducted under paragraph (2)(D).

(f)¹ STANDARDS.—

(1) IN GENERAL.—The Secretary shall issue standards to assure consistent performance by laboratories issued a certificate under this section of valid and reliable laboratory examinations and other procedures. Such standards shall require each laboratory issued a certificate under this section—

(A) to maintain a quality assurance and quality control program adequate and appropriate for the validity and reliability of the laboratory examinations and other procedures of the laboratory and to meet requirements relating to the proper collection, transportation, and storage of specimens and the reporting of results,

(B) to maintain records, equipment, and facilities necessary for the proper and effective operation of the laboratory,

¹ Section 3 of Public Law 100-578 provides that, with respect to subsection (g)(1) and subsections (h) through (m), any reference made in any of such subsections to the standards established under subsection (f) "shall be considered a reference to the standards established under subsection (d) [of section 353], as in effect on December 31, 1988."

(C)¹ in performing and carrying out its laboratory examinations and other procedures, to use only personnel meeting such qualifications as the Secretary may establish for the direction, supervision, and performance of examinations and procedures within the laboratory, which qualifications shall take into consideration competency, training, experience, job performance, and education and which qualifications shall, as appropriate, be different on the basis of the type of examinations and procedures being performed by the laboratory and the risks and consequences of erroneous results associated with such examinations and procedures,

(D) to qualify under a proficiency testing program meeting the standards established by the Secretary under paragraph (3), and

(E) to meet such other requirements as the Secretary determines necessary to assure consistent performance by such laboratories of accurate and reliable laboratory examinations and procedures.

(2) CONSIDERATIONS.—In developing the standards to be issued under paragraph (1), the Secretary shall, within the flexibility provided under subparagraphs (A) through (E) of paragraph (1), take into consideration—

(A) the examinations and procedures performed and the methodologies employed,

(B) the degree of independent judgment involved,

(C) the amount of interpretation involved,

(D) the difficulty of the calculations involved,

(E) the calibration and quality control requirements of the instruments used,

(F) the type of training required to operate the instruments used in the methodology, and

(G) such other factors as the Secretary considers relevant.

(3) PROFICIENCY TESTING PROGRAM.—

(A) IN GENERAL.—The Secretary shall establish standards for the proficiency testing programs for laboratories issued a certificate under this section which are conducted by the Secretary, conducted by an organization approved under subparagraph (C), or conducted by an approved accrediting body. The standards shall require that a laboratory issued a certificate under this section be tested for each examination and procedure conducted within a category of examinations or procedures for which it has received a certificate, except for examinations and procedures for which the Secretary has determined that a proficiency test cannot reasonably be developed. The testing shall be conducted on a quarterly basis, except where the Secretary determines for technical and scientific reasons that a particular examination or procedure may be tested less frequently (but not less often than twice per year).

¹Section 3 of Public Law 100-578 provides that, if a laboratory was not subject to the requirements of section 353 as in effect on December 31, 1988, subsections (f)(1)(C) and (g)(2) (above) shall take effect with respect to the laboratory on July 1, 1991.

(B) CRITERIA.—The standards established under subparagraph (A) shall include uniform criteria for acceptable performance under a proficiency testing program, based on the available technology and the clinical relevance of the laboratory examination or other procedure subject to such program. The criteria shall be established for all examinations and procedures and shall be uniform for each examination and procedure. The standards shall also include a system for grading proficiency testing performance to determine whether a laboratory has performed acceptably for a particular quarter and acceptably for a particular examination or procedure or category of examination or procedure over a period of successive quarters.

(C) APPROVED PROFICIENCY TESTING PROGRAMS.—For the purpose of administering proficiency testing programs which meet the standards established under subparagraph (A), the Secretary shall approve a proficiency testing program offered by a private nonprofit organization or a State if the program meets the standards established under subparagraph (A) and the organization or State provides technical assistance to laboratories seeking to qualify under the program. The Secretary shall evaluate each program approved under this subparagraph annually to determine if the program continues to meet the standards established under subparagraph (A) and shall withdraw the approval of any program that no longer meets such standards.

(D) ON-SITE¹ TESTING.—The Secretary shall perform, or shall direct a program approved under subparagraph (C) to perform, onsite proficiency testing to assure compliance with the requirements of subsection (d)(5)². The Secretary shall perform, on an onsite or other basis, proficiency testing to evaluate the performance of a proficiency testing program approved under subparagraph (C) and to assure quality performance by a laboratory.

(E) TRAINING, TECHNICAL ASSISTANCE, AND ENHANCED PROFICIENCY TESTING.—The Secretary may, in lieu of or in addition to actions authorized under subsection (h), (i), or (j), require any laboratory which fails to perform acceptably on an individual examination and procedure or a category of examination and procedures—

(i) to undertake training and to obtain the necessary technical assistance to meet the requirements of the proficiency³ testing program,

(ii) to enroll in a program of enhanced proficiency testing, or

(iii) to undertake any combination of the training, technical assistance, or testing described in clauses (i) and (ii).

(F) TESTING RESULTS.—The Secretary shall establish a system to make the results of the proficiency testing programs subject to the standards established by the Sec-

¹ So in original. Probably should not be hyphenated. Compare with text of subparagraph (D).

² So in original. Probably should be "(d)(1)(E)".

³ So in original. Probably should be "proficiency".

retary under subparagraph (A) available, on a reasonable basis, upon request of any person. The Secretary shall include with results made available under this subparagraph such explanatory information as may be appropriate to assist in the interpretation of such results.

(4) NATIONAL STANDARDS FOR QUALITY ASSURANCE IN CYTOLOGY SERVICES.—

(A) ESTABLISHMENT.—The Secretary shall establish national standards for quality assurance in cytology services designed to assure consistent performance by laboratories of valid and reliable cytological services.

(B) STANDARDS.—The standards established under subparagraph (A) shall include—

(i) the maximum number of cytology slides that any individual may screen in a 24-hour period,

(ii) requirements that a clinical laboratory maintain a record of (I) the number of cytology slides screened during each 24-hour period by each individual who examines cytology slides for the laboratory, and (II) the number of hours devoted during each 24-hour period to screening cytology slides by such individual,

(iii) criteria for requiring rescreening of cytological preparations, such as (I) random rescreening of cytology specimens determined to be in the benign category, (II) focused rescreening of such preparations in high risk groups, and (III) for each abnormal cytological result, rescreening of all prior cytological specimens for the patient, if available,

(iv) periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site¹ proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions,

(v) procedures for detecting inadequately prepared slides, for assuring that no cytological diagnosis is rendered on such slides, and for notifying referring physicians of such slides,

(vi) requirements that all cytological screening be done on the premises of a laboratory that is certified under this section,

(vii) requirements for the retention of cytology slides by laboratories for such periods of time as the Secretary considers appropriate, and

(viii) standards requiring periodic inspection of cytology services by persons capable of evaluating the quality of cytology services.

(g) INSPECTIONS.—

(1) IN GENERAL.—The Secretary may, on an announced or unannounced basis, enter and inspect, during regular hours of

¹So in original. See footnote 1 on page 195.

operation, laboratories which have been issued a certificate under this section. In conducting such inspections the Secretary shall have access to all facilities, equipment, materials, records, and information that the Secretary determines have a bearing on whether the laboratory is being operated in accordance with this section. As part of such an inspection the Secretary may copy any such material or require to it be¹ submitted to the Secretary. An inspection under this paragraph may be made only upon presenting identification to the owner, operator, or agent in charge of the laboratory being inspected.

(2)² COMPLIANCE WITH REQUIREMENTS AND STANDARDS.—The Secretary shall conduct inspections of laboratories under paragraph (1) to determine their compliance with the requirements of subsection (d) and the standards issued under subsection (f). Inspections of laboratories not accredited under subsection (e) shall be conducted on a biennial basis or with such other frequency as the Secretary determines to be necessary to assure compliance with such requirements and standards. Inspections of laboratories accredited under subsection (e) shall be conducted on such basis as the Secretary determines is necessary to assure compliance with such requirements and standards.

(h) INTERMEDIATE SANCTIONS.—

(1) IN GENERAL.—If the Secretary determines that a laboratory which has been issued a certificate under this section no longer substantially meets the requirements for the issuance of a certificate, the Secretary may impose intermediate sanctions in lieu of the actions authorized by subsection (i).

(2) TYPES OF SANCTIONS.—The intermediate sanctions which may be imposed under paragraph (1) shall consist of—

(A) directed plans of correction,

(B) civil money penalties in an amount not to exceed \$10,000 for each violation listed in subsection (i)(1) or for each day of substantial noncompliance with the requirements of this section,

(C) payment for the costs of onsite monitoring, or

(D) any combination of the actions described in subparagraphs (A), (B), and (C).

(3) PROCEDURES.—The Secretary shall develop and implement procedures with respect to when and how each of the intermediate sanctions is to be imposed under paragraph (1). Such procedures shall provide for notice to the laboratory and a reasonable opportunity to respond to the proposed sanction and appropriate procedures for appealing determinations relating to the imposition of intermediate sanctions³

(i) SUSPENSION, REVOCATION, AND LIMITATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), the certificate of a laboratory issued under this section may be suspended, revoked, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or opera-

¹ So in original. Probably should be "require it to be".

² See footnote 1 on page 194.

³ So in original. The sentence lacks a period.

tor of the laboratory, that such owner or operator or any employee of the laboratory—

(A) has been guilty of misrepresentation in obtaining the certificate,

(B) has performed or represented the laboratory as entitled to perform a laboratory examination or other procedure which is not within a category of laboratory examinations or other procedures authorized in the certificate,

(C) has failed to comply with the requirements of subsection (d) or the standards prescribed by the Secretary under subsection (f),

(D) has failed to comply with reasonable requests of the Secretary for—

(i) any information or materials, or

(ii) work on materials,

that the Secretary concludes is necessary to determine the laboratory's continued eligibility for its certificate or continued compliance with the Secretary's standards under subsection (f),

(E) has refused a reasonable request of the Secretary, or any Federal officer or employee duly designated by the Secretary, for permission to inspect the laboratory and its operations and pertinent records during the hours the laboratory is in operation,

(F) has violated or aided and abetted in the violation of any provisions of this section or of any regulation promulgated thereunder, or

(G) has not complied with an intermediate sanction imposed under subsection (h).

(2) ACTION BEFORE A HEARING.—If the Secretary determines that—

(A) the failure of a laboratory to comply with the standards of the Secretary under subsection (f) presents an imminent and serious risk to human health, or

(B) a laboratory has engaged in an action described in subparagraph (D) or (E) of paragraph (1),

the Secretary may suspend or limit the certificate of the laboratory before holding a hearing under paragraph (1) regarding such failure or refusal. The opportunity for a hearing shall be provided no later than 60 days from the effective date of the suspension or limitation. A suspension or limitation under this paragraph shall stay in effect until the decision of the Secretary made after the hearing under paragraph (1).

(3) INELIGIBILITY TO OWN OR OPERATE LABORATORIES AFTER REVOCATION.—No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section. The certificate of a laboratory which has been excluded from participation under the medicare program under title XVIII of the Social Security Act because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded.

(4) **IMPROPER REFERRALS.**—Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year and shall be subject to appropriate fines and penalties as provided for in subsection (h).

(j) **INJUNCTIONS.**—Whenever the Secretary has reason to believe that continuation of any activity by a laboratory would constitute a significant hazard to the public health the Secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity. Upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this subsection shall be granted without bond by such court.

(k) **JUDICIAL REVIEW.**—

(1) **PETITION.**—Any laboratory which has had an intermediate sanction imposed under subsection (h) or has had its certificate suspended, revoked, or limited under subsection (i) may, at any time within 60 days after the date the action of the Secretary under subsection (i) or (h) becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has its principal place of business for judicial review of such action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary for that purpose. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

(2) **ADDITIONAL EVIDENCE.**—If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal of such additional evidence) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file such modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of his original action, with the return of such additional evidence.

(3) **JUDGMENT OF COURT.**—Upon the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) **FINALITY OF JUDGMENT.**—The judgment of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certifi-

cation as provided in section 1254 of title 28, United States Code.

(l) SANCTIONS.—Any person who intentionally violates any requirement of this section or any regulation promulgated thereunder shall be imprisoned for not more than one year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

(m) FEES.—

(1) CERTIFICATE FEES.—The Secretary shall require payment of fees for the issuance and renewal of certificates, except that the Secretary shall only require a nominal fee for the issuance and renewal of certificates of waiver.

(2) ADDITIONAL FEES.—The Secretary shall require the payment of fees for inspections of laboratories which are not accredited and for the cost of performing proficiency testing on laboratories which do not participate in proficiency testing programs approved under subsection (f)(3)(C).

(3) CRITERIA.—

(A) FEES UNDER PARAGRAPH (1).—Fees imposed under paragraph (1) shall be sufficient to cover the general costs of administering this section, including evaluating and monitoring proficiency testing programs approved under subsection (f) and accrediting bodies and implementing and monitoring compliance with the requirements of this section.

(B) FEES UNDER PARAGRAPH (2).—Fees imposed under paragraph (2) shall be sufficient to cover the cost of the Secretary in carrying out the inspections and proficiency testing described in paragraph (2).

(C) FEES IMPOSED UNDER PARAGRAPHS (1) AND (2).—Fees imposed under paragraphs (1) and (2) shall vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant, which may include the dollar volume and scope of the testing being performed by the laboratories.

(n) INFORMATION.—On April 1, 1990 and annually thereafter, the Secretary shall compile and make available to physicians and the general public information, based on the previous calendar year, which the Secretary determines is useful in evaluating the performance of a laboratory, including—

(1) a list of laboratories which have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks,

(2) a list of laboratories—

(A) which have had their certificates revoked, suspended, or limited under subsection (i), or

(B) which have been the subject of a sanction under subsection (l),

together with a statement of the reasons for the revocation, suspension, limitation, or sanction,

(3) a list of laboratories subject to intermediate sanctions under subsection (h) together with a statement of the reasons for the sanctions,

(4) a list of laboratories whose accreditation has been withdrawn or revoked together with a statement of the reasons for the withdrawal or revocation,

(5) a list of laboratories against which the Secretary has taken action under subsection (j) together with a statement of the reasons for such action, and

(6) a list of laboratories which have been excluded from participation under title XVIII or XIX of the Social Security Act.

The information to be compiled under paragraphs (1) through (6) shall be information for the calendar year preceding the date the information is to be made available to the public and shall be accompanied by such explanatory information as may be appropriate to assist in the interpretation of the information compiled under such paragraphs.

(o) DELEGATION.—In carrying out this section, the Secretary may, pursuant to agreement, use the services or facilities of any Federal or State or local public agency or nonprofit private organization, and may pay therefor in advance or by way of reimbursement, and in such installments, as the Secretary may determine.

(p) STATE LAWS.—

(1) Except as provided in paragraph (2), nothing in this section shall be construed as affecting the power of any State to enact and enforce laws relating to the matters covered by this section to the extent that such laws are not inconsistent with this section or with the regulations issued under this section.

(2) If a State enacts laws relating to matters covered by this section which provide for requirements equal to or more stringent than the requirements of this section or than the regulations issued under this section, the Secretary may exempt clinical laboratories in that State from compliance with this section.

(q) CONSULTATIONS.—In carrying out this section, the Secretary shall consult with appropriate private organizations and public agencies.

Subpart 3—Mammography Facilities

SEC. 354. CERTIFICATION OF MAMMOGRAPHY FACILITIES.

(a) DEFINITIONS.—As used in this section:

(1) ACCREDITATION BODY.—The term “accreditation body” means a body that has been approved by the Secretary under subsection (e)(1)(A) to accredit mammography facilities.

(2) CERTIFICATE.—The term “certificate” means the certificate described in subsection (b)(1).

(3) FACILITY.—

(A) IN GENERAL.—The term “facility” means a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility as determined by the Secretary, that conducts breast cancer

screening or diagnosis through mammography activities. Such term does not include a facility of the Department of Veterans Affairs.

(B) ACTIVITIES.—For the purposes of this section, the activities of a facility include the operation of equipment to produce the mammogram, the processing of the film, the initial interpretation of the mammogram and the viewing conditions for that interpretation. Where procedures such as the film processing, or the interpretation of the mammogram are performed in a location different from where the mammogram is performed, the facility performing the mammogram shall be responsible for meeting the quality standards described in subsection (f).

(4) INSPECTION.—The term “inspection” means an onsite evaluation of the facility by the Secretary, or State agency on behalf of the Secretary.

(5) MAMMOGRAM.—The term “mammogram” means a radiographic image produced through mammography.

(6) MAMMOGRAPHY.—The term “mammography” means radiography of the breast.

(7) SURVEY.—The term “survey” means an onsite physics consultation and evaluation performed by a medical physicist as described in subsection (f)(1)(E).

(b) CERTIFICATE REQUIREMENT.—

(1) CERTIFICATE.—No facility may conduct an examination or procedure described in paragraph (2) involving mammography after October 1, 1994, unless the facility obtains—

(A) a certificate—

(i) that is issued, and, if applicable, renewed, by the Secretary in accordance with subsection (c)(1);

(ii) that is applicable to the examination or procedure to be conducted; and

(iii) that is displayed prominently in such facility;

or

(B) a provisional certificate—

(i) that is issued by the Secretary in accordance with subsection (c)(2);

(ii) that is applicable to the examination or procedure to be conducted; and

(iii) that is displayed prominently in such facility.

The reference to a certificate in this section includes a provisional certificate.

(2) EXAMINATION OR PROCEDURE.—A facility shall obtain a certificate in order to—

(A) operate radiological equipment that is used to image the breast;

(B) provide for the interpretation of a mammogram produced by such equipment at the facility or under arrangements with a qualified individual at a facility different from where the mammography examination is performed; and

(C) provide for the processing of film produced by such equipment at the facility or under arrangements with a

qualified individual at a facility different from where the mammography examination is performed.

(c) ISSUANCE AND RENEWAL OF CERTIFICATES.—

(1) IN GENERAL.—The Secretary may issue or renew a certificate for a facility if the person or agent described in subsection (d)(1)(A) meets the applicable requirements of subsection (d)(1) with respect to the facility. The Secretary may issue or renew a certificate under this paragraph for not more than 3 years.

(2) PROVISIONAL CERTIFICATE.—The Secretary may issue a provisional certificate for an entity to enable the entity to qualify as a facility. The applicant for a provisional certificate shall meet the requirements of subsection (d)(1), except providing information required by clauses (iii) and (iv) of subsection (d)(1)(A). A provisional certificate may be in effect no longer than 6 months from the date it is issued, except that it may be extended once for a period of not more than 90 days if the owner, lessor, or agent of the facility demonstrates to the Secretary that without such extension access to mammography in the geographic area served by the facility would be significantly reduced and if the owner, lessor, or agent of the facility will describe in a report to the Secretary steps that will be taken to qualify the facility for certification under subsection (b)(1).

(d) APPLICATION FOR CERTIFICATE.—

(1) SUBMISSION.—The Secretary may issue or renew a certificate for a facility if—

(A) the person who owns or leases the facility or an authorized agent of the person, submits to the Secretary, in such form and manner as the Secretary shall prescribe, an application that contains at a minimum—

(i) a description of the manufacturer, model, and type of each x-ray machine, image receptor, and processor operated in the performance of mammography by the facility;

(ii) a description of the procedures currently used to provide mammography at the facility, including—

(I) the types of procedures performed and the number of such procedures performed in the prior 12 months;

(II) the methodologies for mammography; and

(III) the names and qualifications (educational background, training, and experience) of the personnel performing mammography and the physicians reading and interpreting the results from the procedures;

(iii) proof of on-site survey by a qualified medical physicist as described in subsection (f)(1)(E); and

(iv) proof of accreditation in such manner as the Secretary shall prescribe; and

(B) the person or agent submits to the Secretary—

(i) a satisfactory assurance that the facility will be operated in accordance with standards established by

the Secretary under subsection (f) to assure the safety and accuracy of mammography;

(ii) a satisfactory assurance that the facility will—

(I) permit inspections under subsection (g);

(II) make such records and information available, and submit such reports, to the Secretary as the Secretary may require; and

(III) update the information submitted under subparagraph (A) or assurances submitted under this subparagraph on a timely basis as required by the Secretary; and

(iii) such other information as the Secretary may require.

An applicant shall not be required to provide in an application under subparagraph (A) any information which the applicant has supplied to the accreditation body which accredited the applicant, except as required by the Secretary.

(2) APPEAL.—If the Secretary denies an application for the certification of a facility submitted under paragraph (1)(A), the Secretary shall provide the owner or lessor of the facility or the agent of the owner or lessor who submitted such application—

(A) a statement of the grounds on which the denial is based, and

(B) an opportunity for an appeal in accordance with the procedures set forth in regulations of the Secretary published at 42 C.F.R. 498 and in effect on the date of the enactment of this section.

(3) EFFECT OF DENIAL.—If the application for the certification of a facility is denied, the facility may not operate unless the denial of the application is overturned at the conclusion of the administrative appeals process provided in the regulations referred to in paragraph (2)(B).

(e) ACCREDITATION.—

(1) APPROVAL OF ACCREDITATION BODIES.—

(A) IN GENERAL.—The Secretary may approve a private nonprofit organization or State agency to accredit facilities for purposes of subsection (d)(1)(A)(iv) if the accreditation body meets the standards for accreditation established by the Secretary as described in subparagraph (B) and provides the assurances required by subparagraph (C).

(B) STANDARDS.—The Secretary shall establish standards for accreditation bodies, including—

(i) standards that require an accreditation body to perform—

(I) a review of clinical images from each facility accredited by such body not less often than every 3 years which review will be made by qualified practicing physicians; and

(II) a review of a random sample of clinical images from such facilities in each 3-year period beginning October 1, 1994, which review will be made by qualified practicing physicians;

(ii) standards that prohibit individuals conducting the reviews described in clause (i) from maintaining

any financial relationship to the facility undergoing review which would constitute a conflict of interest;

(iii) standards that limit the imposition of fees for accreditation to reasonable amounts;

(iv) standards that require as a condition of accreditation that each facility undergo a survey at least annually by a medical physicist as described in subsection (f)(1)(E) to ensure that the facility meets the standards described in subparagraphs (A) and (B) of subsection (f)(1);

(v) standards that require monitoring and evaluation of such survey, as prescribed by the Secretary;

(vi) standards that are equal to standards established under subsection (f) which are relevant to accreditation as determined by the Secretary; and

(vii) such additional standards as the Secretary may require.

(C) ASSURANCES.—The accrediting body shall provide the Secretary satisfactory assurances that the body will—

(i) comply with the standards as described in subparagraph (B);

(ii) comply with the requirements described in paragraph (4);

(iii) submit to the Secretary the name of any facility for which the accreditation body denies, suspends, or revokes accreditation;

(iv) notify the Secretary in a timely manner before the accreditation body changes the standards of the body;

(v) notify each facility accredited by the accreditation body if the Secretary withdraws approval of the accreditation body under paragraph (2) in a timely manner; and

(vi) provide such other additional information as the Secretary may require.

(D) REGULATIONS.—Not later than 9 months after the date of the enactment of this section, the Secretary shall promulgate regulations under which the Secretary may approve an accreditation body.

(2) WITHDRAWAL OF APPROVAL.—

(A) IN GENERAL.—The Secretary shall promulgate regulations under which the Secretary may withdraw the approval of an accreditation body if the Secretary determines that the accreditation body does not meet the standards under subparagraph (B) of paragraph (1), the requirements of clauses (i) through (vi) of subparagraph (C) of paragraph (1), or the requirements of paragraph (4).

(B) EFFECT OF WITHDRAWAL.—If the Secretary withdraws the approval of an accreditation body under subparagraph (A), the certificate of any facility accredited by the body shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain another accreditation.

(3) ACCREDITATION.—To be accredited by an approved accreditation body a facility shall meet—

(A) the standards described in paragraph (1)(B) which the Secretary determines are applicable to the facility, and

(B) such other standards which the accreditation body may require.

(4) COMPLIANCE.—To ensure that facilities accredited by an accreditation body will continue to meet the standards of the accreditation body, the accreditation body shall—

(A) make onsite visits on an annual basis of a sufficient number of the facilities accredited by the body to allow a reasonable estimate of the performance of the body; and

(B) take such additional measures as the Secretary determines to be appropriate.

Visits made under subparagraph (A) shall be made after providing such notice as the Secretary may require.

(5) REVOCATION OF ACCREDITATION.—If an accreditation body revokes the accreditation of a facility, the certificate of the facility shall continue in effect until such time as may be determined by the Secretary.

(6) EVALUATION AND REPORT.—

(A) EVALUATION.—The Secretary shall evaluate annually the performance of each approved accreditation body by—

(i) inspecting under subsection (g)(2) a sufficient number of the facilities accredited by the body to allow a reasonable estimate of the performance of the body; and

(ii) such additional means as the Secretary determines to be appropriate.

(B) REPORT.—The Secretary shall annually prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes the results of the evaluation conducted in accordance with subparagraph (A).

(f) QUALITY STANDARDS.—

(1) IN GENERAL.—The standards referred to in subsection (d)(1)(B)(i) are standards established by the Secretary which include—

(A) standards that require establishment and maintenance of a quality assurance and quality control program at each facility that is adequate and appropriate to ensure the reliability, clarity, and accuracy of interpretation of mammograms and standards for appropriate radiation dose;

(B) standards that require use of radiological equipment specifically designed for mammography, including radiologic standards and standards for other equipment and materials used in conjunction with such equipment;

(C) a requirement that personnel who perform mammography—

(i)(I) be licensed by a State to perform radiological procedures; or

(II) be certified as qualified to perform radiological procedures by an organization described in paragraph (2)(A); and

(ii) during the 2-year period beginning October 1, 1994, meet training standards for personnel who perform mammography or meet experience requirements which shall at a minimum include 1 year of experience in the performance of mammography; and

(iii) upon the expiration of such 2-year period meet minimum training standards for personnel who perform mammograms;

(D) a requirement that mammograms be interpreted by a physician who is certified as qualified to interpret radiological procedures, including mammography—

(i)(I) by a board described in paragraph (2)(B); or

(II) by a program that complies with the standards described in paragraph (2)(C); and

(ii) who meets training and continuing medical education requirements as established by the Secretary;

(E) a requirement that individuals who survey mammography facilities be medical physicists—

(i) licensed or approved by a State to perform such surveys, reviews, or inspections for mammography facilities;

(ii) certified in diagnostic radiological physics or certified as qualified to perform such surveys by a board as described in paragraph (2)(D); or

(iii) in the first 5 years after the date of the enactment of this section, who meet other criteria established by the Secretary which are comparable to the criteria described in clause (i) or (ii);

(F) a requirement that a medical physicist who is qualified in mammography as described in subparagraph (E) survey mammography equipment and oversee quality assurance practices at each facility;

(G) a requirement that—

(i) a facility that performs any mammogram maintain the mammogram in the permanent medical records of the patient—

(I) for a period of not less than 5 years, or not less than 10 years if no additional mammograms of such patient are performed at the facility, or longer if mandated by State law; or

(II) until such time as the patient should request that the patient's medical records be forwarded to a medical institution or a physician of the patient;

whichever is longer; and

(ii)(I) a facility must assure the preparation of a written report of the results of any mammography examination signed by the interpreting physician;

(II) such written report shall be provided to the patient's physicians (if any);

(III) if such a physician is not available or if there is no such physician, the written report shall be sent directly to the patient; and

(IV) if such report is sent to the patient, the report shall include a summary written in terms easily understood by a lay person; and

(H) standards relating to special techniques for mammography of patients with breast implants.

Subparagraph (G) shall not be construed to limit a patient's access to the patient's medical records.

(2) CERTIFICATION OF PERSONNEL.—The Secretary shall by regulation—

(A) specify organizations eligible to certify individuals to perform radiological procedures as required by paragraph (1)(C);

(B) specify boards eligible to certify physicians to interpret radiological procedures, including mammography, as required by paragraph (1)(D);

(C) establish standards for a program to certify physicians described in paragraph (1)(D); and

(D) specify boards eligible to certify medical physicists who are qualified to survey mammography equipment and to oversee quality assurance practices at mammography facilities.

(g) INSPECTIONS.—

(1) ANNUAL INSPECTIONS.—

(A) IN GENERAL.—The Secretary may enter and inspect certified facilities to determine compliance with the standards established under subsection (f). The Secretary shall, if feasible, delegate to a State agency the authority to make such inspections.

(B) IDENTIFICATION.—The Secretary, or State agency acting on behalf of the Secretary, may conduct inspections only on presenting identification to the owner, operator, or agent in charge of the facility to be inspected.

(C) SCOPE OF INSPECTION.—In conducting inspections, the Secretary or State agency acting on behalf of the Secretary—

(i) shall have access to all equipment, materials, records, and information that the Secretary or State agency considers necessary to determine whether the facility is being operated in accordance with this section; and

(ii) may copy, or require the facility to submit to the Secretary or the State agency, any of the materials, records, or information.

(D) QUALIFICATIONS OF INSPECTORS.—Qualified individuals, as determined by the Secretary, shall conduct all inspections. The Secretary may request that a State agency acting on behalf of the Secretary designate a qualified officer or employee to conduct the inspections, or designate a qualified Federal officer or employee to conduct inspec-

tions. The Secretary shall establish minimum qualifications and appropriate training for inspectors and criteria for certification of inspectors in order to inspect facilities for compliance with subsection (f).

(E) FREQUENCY.—The Secretary or State agency acting on behalf of the Secretary shall conduct inspections under this paragraph of each facility not less often than annually.

(F) RECORDS AND ANNUAL REPORTS.—The Secretary or a State agency acting on behalf of the Secretary which is responsible for inspecting mammography facilities shall maintain records of annual inspections required under this paragraph for a period as prescribed by the Secretary. Such a State agency shall annually prepare and submit to the Secretary a report concerning the inspections carried out under this paragraph. Such reports shall include a description of the facilities inspected and the results of such inspections.

(2) INSPECTION OF ACCREDITED FACILITIES.—The Secretary shall inspect annually a sufficient number of the facilities accredited by an accreditation body to provide the Secretary with a reasonable estimate of the performance of such body.

(3) INSPECTION OF FACILITIES INSPECTED BY STATE AGENCIES.—The Secretary shall inspect annually facilities inspected by State agencies acting on behalf of the Secretary to assure a reasonable performance by such State agencies.

(4) TIMING.—The Secretary, or State agency, may conduct inspections under paragraphs (1), (2), and (3), during regular business hours or at a mutually agreeable time and after providing such notice as the Secretary may prescribe, except that the Secretary may waive such requirements if the continued performance of mammography at such facility threatens the public health.

(5) LIMITED REINSPECTION.—Nothing in this section limits the authority of the Secretary to conduct limited reinspections of facilities found not to be in compliance with this section.

(h) SANCTIONS.—

(1) IN GENERAL.—In order to promote voluntary compliance with this section, the Secretary may, in lieu of taking the actions authorized by subsection (i), impose one or more of the following sanctions:

(A) Directed plans of correction which afford a facility an opportunity to correct violations in a timely manner.

(B) Payment for the cost of onsite monitoring.

(2) CIVIL MONEY PENALTIES.—The Secretary may assess civil money penalties in an amount not to exceed \$10,000 for—

(A) failure to obtain a certificate as required by subsection (b),

(B) each failure by a facility to substantially comply with, or each day on which a facility fails to substantially comply with, the standards established under subsection (f) or the requirements described in subclauses (I) through (III) of subsection (d)(1)(B)(ii), and

(C) each violation, or for each aiding and abetting in a violation of, any provision of, or regulation promulgated under, this section by an owner, operator, or any employee of a facility required to have a certificate.

(3) PROCEDURES.—The Secretary shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed under paragraphs (1) and (2). Such procedures shall provide for notice to the owner or operator of the facility and a reasonable opportunity for the owner or operator to respond to the proposed sanctions and appropriate procedures for appealing determinations relating to the imposition of sanctions.

(i) SUSPENSION AND REVOCATION.—

(1) IN GENERAL.—The certificate of a facility issued under subsection (c) may be suspended or revoked if the Secretary finds, after providing, except as provided in paragraph (2), reasonable notice and an opportunity for a hearing to the owner or operator of the facility, that the owner, operator, or any employee of the facility—

(A) has been guilty of misrepresentation in obtaining the certificate;

(B) has failed to comply with the requirements of subsection (d)(1)(B)(ii)(III) or the standards established by the Secretary under subsection (f);

(C) has failed to comply with reasonable requests of the Secretary for any record, information, report, or material that the Secretary concludes is necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards established under subsection (f);

(D) has refused a reasonable request of the Secretary, any Federal officer or employee duly designated by the Secretary, or any State officer or employee duly designated by the State, for permission to inspect the facility or the operations and pertinent records of the facility in accordance with subsection (g);

(E) has violated or aided and abetted in the violation of any provision of, or regulation promulgated under, this section; or

(F) has failed to comply with a sanction imposed under subsection (h).

(2) ACTION BEFORE A HEARING.—

(A) IN GENERAL.—The Secretary may suspend the certificate of the facility before holding a hearing required by paragraph (1) if the Secretary makes the finding described in paragraph (1) and determines that—

(i) the failure of a facility to comply with the standards established by the Secretary under subsection (f) presents a serious risk to human health; or

(ii) a facility has engaged in an action described in subparagraph (D) or (E) of paragraph (1).

(B) HEARING.—If the Secretary suspends a certificate under subparagraph (A), the Secretary shall provide an opportunity for a hearing to the owner or operator of the fa-

cility not later than 60 days from the effective date of the suspension. The suspension shall remain in effect until the decision of the Secretary made after the hearing.

(3) INELIGIBILITY TO OWN OR OPERATE FACILITIES AFTER REVOCATION.—If the Secretary revokes the certificate of a facility on the basis of an act described in paragraph (1), no person who owned or operated the facility at the time of the act may, within 2 years of the revocation of the certificate, own or operate a facility that requires a certificate under this section.

(j) INJUNCTIONS.—If the Secretary determines that—

(1) continuation of any activity related to the provision of mammography by a facility would constitute a serious risk to human health, the Secretary may bring suit in the district court of the United States for the district in which the facility is situated to enjoin continuation of the activity; and

(2) a facility is operating without a certificate as required by subsection (b), the Secretary may bring suit in the district court of the United States for the district in which the facility is situated to enjoin the operation of the facility.

Upon a proper showing, the district court shall grant a temporary injunction or restraining order against continuation of the activity or against operation of a facility, as the case may be, without requiring the Secretary to post a bond, pending issuance of a final order under this subsection.

(k) JUDICIAL REVIEW.—

(1) PETITION.—If the Secretary imposes a sanction on a facility under subsection (h) or suspends or revokes the certificate of a facility under subsection (i), the owner or operator of the facility may, not later than 60 days after the date the action of the Secretary becomes final, file a petition with the United States court of appeals for the circuit in which the facility is situated for judicial review of the action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

(2) ADDITIONAL EVIDENCE.—If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order the additional evidence (and evidence in rebuttal of the additional evidence) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may determine to be proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file the modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of the original action of the Secretary with the return of the additional evidence.

(3) JUDGMENT OF COURT.—Upon the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set the action aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(1) INFORMATION.—

(1) IN GENERAL.—Not later than October 1, 1996, and annually thereafter, the Secretary shall compile and make available to physicians and the general public information that the Secretary determines is useful in evaluating the performance of facilities, including a list of facilities—

(A) that have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks;

(B) that have been subject to sanctions under subsection (h), together with a statement of the reasons for the sanctions;

(C) that have had certificates revoked or suspended under subsection (i), together with a statement of the reasons for the revocation or suspension;

(D) against which the Secretary has taken action under subsection (j), together with a statement of the reasons for the action;

(E) whose accreditation has been revoked, together with a statement of the reasons of the revocation;

(F) against which a State has taken adverse action; and

(G) that meets such other measures of performance as the Secretary may develop.

(2) DATE.—The information to be compiled under paragraph (1) shall be information for the calendar year preceding the date the information is to be made available to the public.

(3) EXPLANATORY INFORMATION.—The information to be compiled under paragraph (1) shall be accompanied by such explanatory information as may be appropriate to assist in the interpretation of the information compiled under such paragraph.

(m) STATE LAWS.—Nothing in this section shall be construed to limit the authority of any State to enact and enforce laws relating to the matters covered by this section that are at least as stringent as this section or the regulations issued under this section.

(n) NATIONAL ADVISORY COMMITTEE.—

(1) ESTABLISHMENT.—In carrying out this section, the Secretary shall establish an advisory committee to be known as the National Mammography Quality Assurance Advisory Committee (hereafter in this subsection referred to as the "Advisory Committee").

(2) COMPOSITION.—The Advisory Committee shall be composed of not fewer than 13, nor more than 19 individuals, who are not officers or employees of the Federal Government. The Secretary shall make appointments to the Advisory Committee from among—

- (A) physicians,
- (B) practitioners, and
- (C) other health professionals,

whose clinical practice, research specialization, or professional expertise include a significant focus on mammography. The Secretary shall appoint at least 4 individuals from among national breast cancer or consumer health organizations with expertise in mammography and at least 2 practicing physicians who provide mammography services.

(3) FUNCTIONS AND DUTIES.—The Advisory Committee shall—

(A) advise the Secretary on appropriate quality standards and regulations for mammography facilities;

(B) advise the Secretary on appropriate standards and regulations for accreditation bodies;

(C) advise the Secretary in the development of regulations with respect to sanctions;

(D) assist in developing procedures for monitoring compliance with standards under subsection (f);

(E) make recommendations and assist in the establishment of a mechanism to investigate consumer complaints;

(F) report on new developments concerning breast imaging that should be considered in the oversight of mammography facilities;

(G) determine whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determine the effects of personnel or other requirements of subsection (f) on access to the services of such facilities in such areas;

(H) determine whether there will exist a sufficient number of medical physicists after October 1, 1999, to assure compliance with the requirements of subsection (f)(1)(E);

(I) determine the costs and benefits of compliance with the requirements of this section (including the requirements of regulations promulgated under this section); and

(J) perform other activities that the Secretary may require.

The Advisory Committee shall report the findings made under subparagraphs (G) and (I) to the Secretary and the Congress no later than October 1, 1993.

(4) MEETINGS.—The Advisory Committee shall meet not less than quarterly for the first 3 years of the program and thereafter, at least biannually.

(5) CHAIRPERSON.—The Secretary shall appoint a chairperson of the Advisory Committee.

(6) CONSULTATIONS.—In carrying out this section, the Secretary shall consult with appropriate Federal agencies within the Department of Health and Human Services for the purposes of de-

veloping standards, regulations, evaluations, and procedures for compliance and oversight.

(p) BREAST CANCER SCREENING SURVEILLANCE RESEARCH GRANTS.—

(1) RESEARCH.—

(A) GRANTS.—The Secretary shall award grants to such entities as the Secretary may determine to be appropriate to establish surveillance systems in selected geographic areas to provide data to evaluate the functioning and effectiveness of breast cancer screening programs in the United States, including assessments of participation rates in screening mammography, diagnostic procedures, incidence of breast cancer, mode of detection (mammography screening or other methods), outcome and follow up information, and such related epidemiologic analyses that may improve early cancer detection and contribute to reduction in breast cancer mortality. Grants may be awarded for further research on breast cancer surveillance systems upon the Secretary's review of the evaluation of the program.

(B) USE OF FUNDS.—Grants awarded under subparagraph (A) may be used—

(i) to study—

(I) methods to link mammography and clinical breast examination records with population-based cancer registry data;

(II) methods to provide diagnostic outcome data, or facilitate the communication of diagnostic outcome data, to radiology facilities for purposes of evaluating patterns of mammography interpretation; and

(III) mechanisms for limiting access and maintaining confidentiality of all stored data; and

(ii) to conduct pilot testing of the methods and mechanisms described in subclauses (I), (II), and (III) of clause (i) on a limited basis.

(C) GRANT APPLICATION.—To be eligible to receive funds under this paragraph, an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(D) REPORT.—A recipient of a grant under this paragraph shall submit a report to the Secretary containing the results of the study and testing conducted under clauses (i) and (ii) of subparagraph (B), along with recommendations for methods of establishing a breast cancer screening surveillance system.

(2) ESTABLISHMENT.—The Secretary shall establish a breast cancer screening surveillance system based on the recommendations contained in the report described in paragraph (1)(D).

(3) STANDARDS AND PROCEDURES.—The Secretary shall establish standards and procedures for the operation of the

breast cancer screening surveillance system, including procedures to maintain confidentiality of patient records.

(4) INFORMATION.—The Secretary shall recruit facilities to provide to the breast cancer screening surveillance system relevant data that could help in the research of the causes, characteristics, and prevalence of, and potential treatments for, breast cancer and benign breast conditions, if the information may be disclosed under section 552 of title 5, United States Code.

(q) STATE PROGRAM.—

(1) IN GENERAL.—The Secretary may, upon application, authorize a State—

(A) to carry out, subject to paragraph (2), the certification program requirements under subsections (b), (c), (d), (g)(1), (h), (i), and (j) (including the requirements under regulations promulgated pursuant to such subsections), and

(B) to implement the standards established by the Secretary under subsection (f),
with respect to mammography facilities operating within the State.

(2) APPROVAL.—The Secretary may approve an application under paragraph (1) if the Secretary determines that—

(A) the State has enacted laws and issued regulations relating to mammography facilities which are the requirements of this section (including the requirements under regulations promulgated pursuant to such subsections), and

(B) the State has provided satisfactory assurances that the State—

(i) has the legal authority and qualified personnel necessary to enforce the requirements of and the regulations promulgated pursuant to this section (including the requirements under regulations promulgated pursuant to such subsections),

(ii) will devote adequate funds to the administration and enforcement of such requirements, and

(iii) will provide the Secretary with such information and reports as the Secretary may require.

(3) AUTHORITY OF SECRETARY.—In a State with an approved application—

(A) the Secretary shall carry out the Secretary's functions under subsections (e) and (f);

(B) the Secretary may take action under subsections (h), (i), and (j); and

(C) the Secretary shall conduct oversight functions under subsections (g)(2) and (g)(3).

(4) WITHDRAWAL OF APPROVAL.—

(A) IN GENERAL.—The Secretary may, after providing notice and opportunity for corrective action, withdraw the approval of a State's authority under paragraph (1) if the Secretary determines that the State does not meet the requirements of such paragraph. The Secretary shall pro-

mulgate regulations for the implementation of this subparagraph.

(B) EFFECT OF WITHDRAWAL.—If the Secretary withdraws the approval of a State under subparagraph (A), the certificate of any facility accredited by the State shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain certification by the Secretary.

(r) FUNDING.—

(1) FEES.—

(A) IN GENERAL.—The Secretary shall, in accordance with this paragraph assess and collect fees from persons described in subsection (d)(1)(A) (other than persons who are governmental entities, as determined by the Secretary) to cover the costs of inspections conducted under subsection (g)(1) by the Secretary or a State acting under a delegation under subparagraph (A) of such subsection. Fees may be assessed and collected under this paragraph only in such manner as would result in an aggregate amount of fees collected during any fiscal year which equals the aggregate amount of costs for such fiscal year for inspections of facilities of such persons under subsection (g)(1). A person's liability for fees shall be reasonably based on the proportion of the inspection costs which relate to such person.

(B) DEPOSIT AND APPROPRIATIONS.—

(i) DEPOSIT AND AVAILABILITY.—Fees collected under subparagraph (A) shall be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services as provided in appropriation Acts and shall remain available without fiscal year limitation.

(ii) APPROPRIATIONS.—Fees collected under subparagraph (A) shall be collected and available only to the extent provided in advance in appropriation Acts.

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

(A) to award research grants under subsection (q), such sums as may be necessary for each of the fiscal years 1993 through 1997; and

(B) for the Secretary to carry out other activities which are not supported by fees authorized and collected under paragraph (1), such sums as may be necessary for fiscal year 1993 through 1997.

PART G—QUARANTINE AND INSPECTION

CONTROL OF COMMUNICABLE DISEASES

SEC. 361. [264] (a) The Surgeon General, with the approval of the Secretary is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and en-

forcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

(b) Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General.

(c) Except as provided in subsection (d), regulations prescribed under this section, insofar as they provide for the apprehension, detention, examination, or conditional release of individuals, shall be applicable only to individuals coming into a State or possession from a foreign country or a possession.

(d) On recommendation of the National Advisory Health Council, regulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a communicable stage and (1) to be moving or about to move from a State to another State; or (2) to be a probable source of infection to individuals who, while infected with such disease in a communicable stage, will be moving from a State to another State. Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary. For purposes of this subsection, the term "State" includes, in addition to the several States, only the District of Columbia.

SUSPENSION OF ENTRIES AND IMPORTS FROM DESIGNATED PLACES

SEC. 362. [265] Whenever the Surgeon General determines that by reason of the existence of any communicable disease in a foreign country there is serious danger of the introduction of such disease into the United States, and that this danger is so increased by the introduction of persons or property from such country that a suspension of the right to introduce such persons and property is required in the interest of the public health, the Surgeon General, in accordance with regulations approved by the President, shall have the power to prohibit, in whole or in part, the introduction of persons and property from such countries or places as he shall designate in order to avert such danger, and for such period of time as he may deem necessary for such purpose.

SPECIAL POWERS IN TIME OF WAR

SEC. 363. ¹ [266] To protect the military and naval forces and war workers of the United States, in time of war, against any communicable disease specified in Executive orders as provided in subsection (b) of section 361, the Surgeon General, on recommendation

¹ Under section 3 of Public Law 239, 80th Congress, the date of July 25, 1947, is deemed, for purposes of this section, to be the date of termination of "any state of war heretofore declared by the Congress".

of the National Advisory Health Council, is authorized to provide by regulations for the apprehension and examination, in time of war, of any individual reasonably believed (1) to be infected with such disease in a communicable stage and (2) to be a probable source of infection to members of the armed forces of the United States or to individuals engaged in the production or transportation of arms, munitions, ships, food, clothing, or other supplies for the armed forces. Such regulations may provide that if upon examination any such individual is found to be so infected, he may be detained for such time and in such manner as may be reasonably necessary.

QUARANTINE STATIONS

SEC. 364. [267] (a) Except as provided in title II of the Act of June 15, 1917, as amended (U.S.C., 1940 edition, title 50, secs. 191-194),¹ the Surgeon General shall control, direct, and manage all United States quarantine stations, grounds, and anchorages, designate their boundaries, and designate the quarantine officers to be in charge thereof. With the approval of the President he shall from time to time select suitable sites for and establish such additional stations, grounds, and anchorages in the States and possessions of the United States as in his judgment are necessary to prevent the introduction of communicable diseases into the States and possessions of the United States.

(b) The Surgeon General shall establish the hours during which quarantine service shall be performed at each quarantine station, and, upon application by any interested party, may establish quarantine inspection during the twenty-four hours of the day, or any fraction thereof, at such quarantine stations as, in his opinion, require such extended service. He may restrict the performance of quarantine inspection to hours of daylight for such arriving vessels as cannot, in his opinion, be satisfactorily inspected during hours of darkness. No vessel shall be required to undergo quarantine inspection during the hours of darkness, unless the quarantine officer at such quarantine station shall deem an immediate inspection necessary to protect the public health. Uniformity shall not be required in the hours during which quarantine inspection may be obtained at the various ports of the United States.

(c) The Surgeon General shall fix a reasonable rate of extra compensation for overtime services of employees of the United States Public Health Service, Foreign Quarantine Division, performing overtime duties including the operation of vessels, in connection with the inspection or quarantine treatment of persons (passengers and crews), conveyances, or goods arriving by land, water, or air in the United States or any place subject to the jurisdiction thereof, hereinafter referred to as "employees of the Public Health Service", when required to be on duty between the hours of 6 o'clock postmeridian and 6 o'clock antemeridian (or between the hours of 7 o'clock postmeridian and 7 o'clock antemeridian at stations which have a declared workday of from 7 o'clock antemeridian to 7 o'clock postmeridian), or on Sundays or holidays, such rate, in lieu of compensation under any other provision of law, to be fixed

¹ Now codified to sections 191, 192, 194, and 195 of title 50, United States Code.

at two times the basic hourly rate for each hour that the overtime extends beyond 6 o'clock (or 7 o'clock as the case may be) postmeridian, and two times the basic hourly rate for each overtime hour worked on Sundays or holidays. As used in this subsection, the term "basic hourly rate" shall mean the regular basic rate of pay which is applicable to such employees for work performed within their regular scheduled tour of duty.

(d)(1) The said extra compensation shall be paid to the United States by the owner, agent, consignee, operator, or master or other person in charge of any conveyance, for whom, at his request, services as described in this subsection (hereinafter referred to as overtime service) are performed. If such employees have been ordered to report for duty and have so reported, and the requested services are not performed by reason of circumstances beyond the control of the employees concerned, such extra compensation shall be paid on the same basis as though the overtime services had actually been performed during the period between the time the employees were ordered to report for duty and did so report, and the time they were notified that their services would not be required, and in any case as though their services had continued for not less than one hour. The Surgeon General with the approval of the Secretary of Health, Education, and Welfare may prescribe regulations requiring the owner, agent, consignee, operator, or master or other person for whom the overtime services are performed to file a bond in such amounts and containing such conditions and with such sureties, or in lieu of a bond, to deposit money or obligations of the United States in such amount, as will assure the payment of charges under this subsection, which bond or deposit may cover one or more transactions or all transactions during a specified period: *Provided*, That no charges shall be made for services performed in connection with the inspection of (1) persons arriving by international highways, ferries, bridges, or tunnels, or the conveyances in which they arrive, or (2) persons arriving by aircraft or railroad trains, the operations of which are covered by published schedules, or the aircraft or trains in which they arrive, or (3) persons arriving by vessels operated between Canadian ports and ports on Puget Sound or operated on the Great Lakes and connecting waterways, the operations of which are covered by published schedules, or the vessels in which they arrive.

(2) Moneys collected under this subsection shall be deposited in the Treasury of the United States to the credit of the appropriation charged with the expense of the services, and the appropriations so credited shall be available for the payment of such compensation to the said employees for services so rendered.

CERTAIN DUTIES OF CONSULAR AND OTHER OFFICERS

SEC. 365. [268] (a) Any consular or medical officer of the United States, designated for such purpose by the Secretary, shall make reports to the Surgeon General, on such forms and at such intervals as the Surgeon General may prescribe, of the health conditions at the port or place at which such officer is stationed.

(b) It shall be the duty of the customs officers and of Coast Guard officers to aid in the enforcement of quarantine rules and regulations; but no additional compensation, except actual and nec-

essary traveling expenses, shall be allowed any such officer by reason of such services.

BILLS OF HEALTH

SEC. 366. [269] (a) Except as otherwise prescribed in regulations, any vessel at any foreign port or place clearing or departing for any port or place in a State or possession shall be required to obtain from the consular officer of the United States or from the Public Health Service officer, or other medical officer of the United States designated by the Surgeon General, at the port or place of departure, a bill of health in duplicate, in the form prescribed by the Surgeon General. The President, from time to time, shall specify the ports at which a medical officer shall be stationed for this purpose. Such bill of health shall set forth the sanitary history and condition of said vessel, and shall state that it has in all respects complied with the regulations prescribed pursuant to subsection (c). Before granting such duplicate bill of health, such consular or medical officer shall be satisfied that the matters and things therein stated are true. The consular officer shall be entitled to demand and receive the fees for bills of health and such fees shall be established by regulation.

(b) Original bills of health shall be delivered to the collectors of customs at the port of entry. Duplicate copies of such bills of health shall be delivered at the time of inspection to quarantine officers at such port. The bills of health herein prescribed shall be considered as part of the ship's papers, and when duly certified to by the proper consular or other officer of the United States, over his official signature and seal, shall be accepted as evidence of the statements therein contained in any court of the United States.

(c) The Surgeon General shall from time to time prescribe regulations, applicable to vessels referred to in subsection (a) of this section for the purpose of preventing the introduction into the States or possessions of the United States of any communicable disease by securing the best sanitary condition of such vessels, their cargoes, passengers, and crews. Such regulations shall be observed by such vessels prior to departure, during the course of the voyage, and also during inspection, disinfection, or other quarantine procedure upon arrival at any United States quarantine station.

(d) The provisions of subsections (a) and (b) of this section shall not apply to vessels plying between such foreign ports on or near the frontiers of the United States and ports of the United States as are designated by treaty.

(e) It shall be unlawful for any vessel to enter any port in any State or possession of the United States to discharge its cargo, or land its passengers, except upon a certificate of the quarantine officer that regulations prescribed under subsection (c) have in all respects been complied with by such officer, the vessel, and its master. The master of every such vessel shall deliver such certificate to the collector of customs at the port of entry, together with the original bill of health and other papers of the vessel. The certificate required by this subsection shall be procurable from the quarantine officer, upon arrival of the vessel at the quarantine station and satisfactory inspection thereof, at any time within which quarantine services are performed at such station.

CIVIL AIR NAVIGATION AND CIVIL AIRCRAFT

SEC. 367. [270] The Surgeon General is authorized to provide by regulations for the application to air navigation and aircraft of any of the provisions of sections 364, 365, and 366 and regulations prescribed thereunder (including penalties and forfeitures for violations of such sections and regulations), to such extent and upon such conditions as he deems necessary for the safeguarding of the public health.

PENALTIES

SEC. 368. [271] (a) Any person who violates any regulation prescribed under section 361, 362, or 363, or any provision of section 366 or any regulation prescribed thereunder, or who enters or departs from the limits of any quarantine station, ground, or anchorage in disregard of quarantine rules and regulations or without permission of the quarantine officer in charge, shall be punished by a fine of not more than \$1,000 or by imprisonment for not more than one year, or both.

(b) Any vessel which violates section 366, or any regulations thereunder or under section 364, or which enters within or departs from the limits of any quarantine station, ground, or anchorage in disregard of the quarantine rules and regulations or without permission of the officer in charge, shall forfeit to the United States not more than \$5,000, the amount to be determined by the court, which shall be a lien on such vessel, to be recovered by proceedings in the proper district court of the United States. In all such proceedings the United States attorney shall appear on behalf of the United States; and all such proceedings shall be conducted in accordance with the rules and laws governing cases of seizure of vessels for violation of the revenue laws of the United States.

(c) With the approval of the Secretary, the Surgeon General may, upon application therefor, remit or mitigate any forfeiture provided for under subsection (b) of this section, and he shall have authority to ascertain the facts upon all such applications.

ADMINISTRATION OF OATHS

SEC. 369. [272] Medical officers of the United States, when performing duties as quarantine officers at any port or place within the United States, are authorized to take declarations and administer oaths in matters pertaining to the administration of the quarantine laws and regulations of the United States.

PART H—ORGAN TRANSPLANTS¹

ORGAN PROCUREMENT ORGANIZATIONS

SEC. 371. [273] (a)(1) The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b).

(2) The Secretary may make grants for the establishment, initial operation, consolidation, and expansion of qualified organ procurement organizations described in subsection (b).

¹ See footnote 1 on page 230 regarding an authorization of appropriations for this part.

(3) The Secretary may make grants to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) and other nonprofit private entities for the purpose of carrying out special projects designed to increase the number of organ donors.

(b)(1) A qualified organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2)¹ and—

(A) is a nonprofit entity,

(B) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization,

(C) has an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act for the procurement of kidneys,

(D) has procedures to obtain payment for non-renal organs provided to transplant centers,

(E)² has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire metropolitan statistical area (as specified by the Director of the Office of Management and Budget) or does not include any part of the area,

(F) has a director and such other staff, including the organ donation coordinators and organ procurement specialists necessary to effectively obtain organs from donors in its service area, and

(G) has a board of directors or an advisory board which—
(i) is composed of—

(I) members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area,

(II) members who represent the public residing in such area,

(III) a physician with knowledge, experience, or skill in the field of histocompatibility³ or an individual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility,

(IV) a physician with knowledge or skill in the field of neurology, and

(V) from each transplant center in its service area which has arrangements described in paragraph (2)¹(G) with the organization, a member who is a surgeon who has practicing privileges in such center and who performs organ transplant surgery,

¹ So in original. Probably should be "paragraph (3)".

² So in original. Margin is incorrect. See section 201(c)(1) of Public Law 101-616.

³ So in original. Probably should be "histocompatibility".

(ii) has the authority to recommend policies for the procurement of organs and the other functions described in paragraph (2)¹, and

(iii) has no authority over any other activity of the organization.

(2)(A) Not later than 90 days after the date of the enactment of this paragraph,² the Secretary shall publish in the Federal Register a notice of proposed rulemaking to establish criteria for determining whether an entity meets the requirement established in paragraph (1)(E).

(B) Not later than 1 year after the date of enactment of this paragraph,² the Secretary shall publish in the Federal Register a final rule to establish the criteria described in subparagraph (A).

(3) An organ procurement organization shall—

(A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations,

(B) conduct and participate in systematic efforts, including professional education, to acquire all usable organs from potential donors,

(C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section 372(b)(2)(E), including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,

(D) arrange for the appropriate tissue typing of donated organs,

(E) have a system to allocate donated organs equitably among transplant patients according to established medical criteria,

(F) provide or arrange for the transportation of donated organs to transplant centers,

(G) have arrangements to coordinate its activities with transplant centers in its service area,

(H) participate in the Organ Procurement Transplantation Network established under section 372,

(I) have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all usable tissues are obtained from potential donors,

(J) evaluate annually the effectiveness of the organization in acquiring potentially available organs, and

(K) assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

¹ See footnote 1 on page 222.

² Enacted November 16, 1990. See section 201(d) of Public Law 101-616.

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

SEC. 372. [274] (a) The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). The amount provided under such contract in any fiscal year may not exceed \$2,000,000. Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984.

(b)(1) The Organ Procurement and Transplantation Network shall carry out the functions described in paragraph (2) and shall—

(A) be a private nonprofit entity that has an expertise in organ procurement and transplantation, and

(B) have a board of directors—

(i) that includes representatives of organ procurement organizations (including organizations that have received grants under section 371), transplant centers, voluntary health associations, and the general public; and

(ii) that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board.

(2) The Organ Procurement and Transplantation Network shall—

(A) establish in one location or through regional centers—

(i) a national list of individuals who need organs, and

(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,

(B) establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,

(C) maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list,

(D) assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients,

(E) adopt and use standards of quality for the acquisition and transportation of donated organs, including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,

(F) prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors,

(G) coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

(H) provide information to physicians and other health professionals regarding organ donation,

(I) collect, analyze, and publish data concerning organ donation and transplants,

(J) carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation, and¹

(K) work actively to increase the supply of donated organs.¹

(L) submit to the Secretary an annual report containing information on the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network.

(c) The Secretary shall establish procedures for—

(1) receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network under subsection (b); and

(2) the consideration by the Secretary of such critical comments.

SCIENTIFIC REGISTRY

SEC. 373. [274a] The Secretary shall, by grant or contract, develop and maintain a scientific registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 376 an analysis of information derived from the registry.

GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS

SEC. 374. [274b] (a) No grant may be made under this part or contract entered into under section 372 or 373 unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

(b)(1) A grant for planning under section 371(a)(1) may be made for one year with respect to any organ procurement organization and may not exceed \$100,000.

(2) Grants under section 371(a)(2) may be made for two years. No such grant may exceed \$500,000 for any year and no organ procurement organization may receive more than \$800,000 for initial operation or expansion.

(3) Grants or contracts under section 371(a)(3) may be made for not more than 3 years.

(c)(1) The Secretary shall determine the amount of a grant or contract made under section 371 or 373. Payments under such grants and contracts may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such install-

¹ So in original. Probably should be no "and" at the end of subparagraph (J), and subparagraph (K) probably should end with ", and" rather than a period. See section 202(b) of Public Law 101-616.

ments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants and contracts.

(2)(A) Each recipient of a grant or contract under section 371 or 373 shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant or contract, the total cost of the undertaking in connection with which such grant or contract was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant or contract under section 371 or 373 that are pertinent to such grant or contract.

(d) For purposes of this part:

(1) The term "transplant center" means a health care facility in which transplants of organs are performed.

(2) The term "organ" means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation and for purposes of section 373, such term includes bone marrow.

ADMINISTRATION

SEC. 375. [274c] The Secretary shall designate and maintain an identifiable administrative unit in the Public Health Service to—

(1) administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act,

(2) conduct a program of public information to inform the public of the need for organ donations,

(3) provide technical assistance to organ procurement organizations, the Organ Procurement and Transplantation Network established under section 372, and other entities in the health care system involved in organ donations, procurement, and transplants, and

(4) provide information—

(i) to patients, their families, and their physicians about transplantation; and

(ii) to patients and their families about the resources available nationally and in each State, and the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network, in order to assist the patients and families with the costs associated with transplantation.

REPORT

SEC. 376. [274d] Not later than February 10 of 1991 and of each second year thereafter, the Secretary shall publish, and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Re-

sources of the Senate.¹ a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.

SEC. 377.² [274f] STUDY BY GENERAL ACCOUNTING OFFICE.

(a) **IN GENERAL.**—The Comptroller General of the United States shall conduct a study for the purpose of determining—

(1) the extent to which the procurement and allocation of organs have been equitable, efficient, and effective;

(2) the problems encountered in the procurement and allocation; and

(3) the effect of State required-request laws.

(b) **REPORT.**—Not later than January 7, 1992, the Comptroller General of the United States shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study.

PART I—NATIONAL BONE MARROW DONOR REGISTRY

SEC. 379. [274k] NATIONAL REGISTRY.

(a) **ESTABLISHMENT.**—The Secretary shall by contract establish and maintain a National Bone Marrow Donor Registry (referred to in this part as the “Registry”) that meets the requirements of this section. The Registry shall be under the general supervision of the Secretary, and under the direction of a board of directors that shall include representatives of marrow donor centers, marrow transplant centers, persons with expertise in the social science, and the general public.

(b) **FUNCTIONS.**—The Registry shall—

(1) establish a system for finding marrow donors suitably matched to unrelated recipients for bone marrow transplantation;

(2) establish a system for patient advocacy, separate from mechanisms for donor advocacy, that directly assists patients, their families, and their physicians in the search for an unrelated marrow donor;

(3) increase the representation of individuals from racial and ethnic minority groups in the pool of potential donors for the Registry in order to enable an individual in a minority group, to the extent practicable, to have a comparable chance of finding a suitable unrelated donor as would an individual not in a minority group;

(4) provide information to physicians, other health care professionals, and the public regarding bone marrow transplantation;

(5) recruit potential bone marrow donors;

¹ So in original. There probably should be a comma after “Senate” rather than a period. See section 205 of Public Law 101-616.

² See footnote 1 on page 230 regarding section 378.

(6) collect, analyze, and publish data concerning bone marrow donation and transplantation; and

(7) support studies and demonstration projects for the purpose of increasing the number of individuals, especially minorities, who are willing to be marrow donors.

(c) **CRITERIA, STANDARDS, AND PROCEDURES.**—Not later than 180 days after the date of enactment of this part, the Secretary shall establish and enforce, for entities participating in the program, including the Registry, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers—

(1) quality standards and standards for tissue typing, obtaining the informed consent of donors, and providing patient advocacy;

(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

(3) procedures to ensure the proper collection and transportation of the marrow;

(4) standards that require the provision of information to patients, their families, and their physicians at the start of the search process concerning—

(A) the resources available through the Registry;

(B) all other marrow donor registries meeting the standards described in this paragraph; and

(C) in the case of the Registry—

(i) the comparative costs of all charges by marrow transplant centers incurred by patients prior to transplantation; and

(ii) the success rates of individual marrow transplant centers;

(5) standards that—

(A) require the establishment of a system of strict confidentiality of records relating to the identity, address, HLA type, and managing marrow donor center for marrow donors and potential marrow donors; and

(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure; and

(6) in the case of a marrow donor center or marrow donor registry participating in the program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Registry.

(d) **COMMENT PROCEDURES.**—The Secretary shall establish and provide information to the public on procedures, which may include establishment of a policy advisory committee, under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Registry is carrying out the duties of the Registry under subsection (b) and complying with the criteria, standards, and procedures described in subsection (c).

(e) **CONSULTATION.**—The Secretary shall consult with the board of directors of the Registry and the bone marrow donor program of the Department of the Navy in developing policies affecting the Registry.

(f) **APPLICATION.**—To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe.

(g) **ELIGIBILITY.**—Entities eligible to receive a contract under this section shall include private nonprofit entities.

(h) **RECORDS.**—

(1) **RECORDKEEPING.**—Each recipient of a contract or subcontract under subsection (a) shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of the contract, the total cost of the undertaking in connection with which the contract was made, and the amount of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) **EXAMINATION OF RECORDS.**—The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

(i) **PENALTIES FOR DISCLOSURE.**—Any person who discloses the content of any record referred to in subsection (c)(5)(A) without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection (c)(5)(B), shall be imprisoned for not more than 2 years or fined in accordance with title 18, United States Code, or both.

(j) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to carry out this section \$15,000,000 for fiscal year 1991 and such sums as may be necessary for each of fiscal years 1992 and 1993.

SEC. 379A. [2741] STUDY BY THE GENERAL ACCOUNTING OFFICE.

(a) **IN GENERAL.**—The Comptroller General of the United States shall conduct a study that evaluates—

(1) the costs and benefits of the search process for an unrelated bone marrow donor among different marrow donor registries;

(2) the extent to which marrow donor registries protect donor confidentiality;

(3) the relationship between the Registry, individual marrow¹ donor centers, and other marrow donor registries;

(4) the effectiveness and appropriateness of policies and procedures of marrow donor centers, marrow transplant centers, and marrow donor registries, including—

(A) the process of donor recruitment, including the policy of asking each donor whether the donor would want to donate more than one time;

¹ So in original. See Public Law 101-616.

(B) the maintenance and updating of donor files; and
(C) the policy of initially typing donors for A/B antigens only instead of initially typing for both A/B and D/R antigens;

(5) the ability of the marrow donor registries to incorporate changes in medical research and clinical practice; and

(6) the costs associated with tissue typing.

(b) REPORT.—Not later than 1 year after the date of enactment of this part, the Comptroller General shall complete the study required under subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the findings made by the study and recommendations for legislative reform.

SEC. 378.¹ [274g] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there are authorized to be appropriated \$8,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

PART J—PREVENTION AND CONTROL OF INJURIES

RESEARCH

SEC. 391. [280b] (a) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall—

(1) conduct, and give assistance to public and nonprofit private entities, scientific institutions, and individuals engaged in the conduct of, research relating to the causes, mechanisms, prevention, diagnosis, treatment of injuries, and rehabilitation from injuries;

(2) make grants to, or enter into cooperative agreements or contracts with, public and nonprofit private entities (including academic institutions, hospitals, and laboratories) and individuals for the conduct of such research; and

(3) make grants to, or enter into cooperative agreements or contracts with, academic institutions for the purpose of providing training on the causes, mechanisms, prevention, diagnosis, treatment of injuries, and rehabilitation from injuries.

(b) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall collect and disseminate, through publications and other appropriate means, information concerning the practical applications of research conducted or assisted under subsection (a). In carrying out the preceding sentence, the Secretary shall disseminate such information to the public, including through elementary and secondary schools.

PREVENTION AND CONTROL ACTIVITIES

SEC. 392. [280b–1] (a) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall—

¹So in original. Section 206(a) of Public Law 101–616 added new sections 377 and 378 to the end of part H. Section 101(a)(2) of the Public Law amended title III by “inserting after section 377” a new part I. The probable intent of the Congress was to insert part I after section 378, and therefore that section 378 provide an authorization of appropriations for part H. (Note that, as a conforming amendment to section 206(a) of the Public Law, section 206(b) struck section 371(c), which provided an authorization of appropriations for grants under section 371(a)).

(1) assist States and political subdivisions of States in activities for the prevention and control of injuries; and

(2) encourage regional activities between States designed to reduce injury rates.

(b) The Secretary, through the Director of the Centers for Disease Control and Prevention, may—

(1) enter into agreements between the Service and public and private community health agencies which provide for cooperative planning of activities to deal with problems relating to the prevention and control of injuries;

(2) work in cooperation with other Federal agencies, and with public and nonprofit private entities, to promote activities regarding the prevention and control of injuries; and

(3) make grants to States and, after consultation with State health agencies, to other public or nonprofit private entities for the purpose of carrying out demonstration projects for the prevention and control of injuries at sites that are not subject to the Occupational Safety and Health Act of 1970, including homes, elementary and secondary schools, and public buildings.

INTERPERSONAL VIOLENCE WITHIN FAMILIES AND AMONG ACQUAINTANCES

SEC. 393. [280b-1a] (a) With respect to activities that are authorized in sections 391 and 392, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out such activities with respect to interpersonal violence within families and among acquaintances. Activities authorized in the preceding sentence include the following:

(1) Collecting data relating to the incidence of such violence.

(2) Making grants to public and nonprofit private entities for the evaluation of programs whose purpose is to prevent such violence, including the evaluation of demonstration projects under paragraph (6).

(3) Making grants to public and nonprofit private entities for the conduct of research on identifying effective strategies for preventing such violence.

(4) Providing to the public information and education on such violence, including information and education to increase awareness of the public health consequences of such violence.

(5) Training health care providers as follows:

(A) To identify individuals whose medical conditions or statements indicate that the individuals are victims of such violence.

(B) To routinely determine, in examining patients, whether the medical conditions or statements of the patients so indicate.

(C) To refer individuals so identified to entities that provide services regarding such violence, including referrals for counseling, housing, legal services, and services of community organizations.

(6) Making grants to public and nonprofit private entities for demonstration projects with respect to such violence, including with respect to prevention.

(b) For purposes of this part, the term "interpersonal violence within families and among acquaintances" includes behavior commonly referred to as domestic violence, sexual assault, spousal abuse, woman battering, partner abuse, elder abuse, and acquaintance rape.

GENERAL PROVISIONS

SEC. 394. [280b-2] (a) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an advisory committee to advise the Secretary and such Director with respect to the prevention and control of injuries.

(b) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may provide technical assistance to public and nonprofit private entities with respect to the planning, development, and operation of any program or service carried out pursuant to this part. The Secretary may provide such technical assistance directly or through grants or contracts.

(c) Not later than February 1 of 1995 and of every second year thereafter, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this part during the preceding 2 fiscal years. Such report shall include a description of such activities that were carried out with respect to interpersonal violence within families and among acquaintances and with respect to rural areas.

AUTHORIZATIONS OF APPROPRIATIONS

SEC. 394A. [280b-3] For the purpose of carrying out this part, there are authorized to be appropriated \$50,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.

PART K—HEALTH CARE SERVICES IN THE HOME

Subpart I—Grants for Demonstration Projects

SEC. 395. [280c] ESTABLISHMENT OF PROGRAM.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make not less than 5, and not more than 20, grants to States for the purpose of assisting grantees in carrying out demonstration projects—

(1) to identify low-income individuals who can avoid institutionalization or prolonged hospitalization if¹ skilled nursing

¹Section 2(f) of Public Law 102-108 (105 Stat. 550) provides as follows: "(f) PUBLIC HEALTH SERVICE ACT TECHNICAL AMENDMENTS.—Section 395. [280c(a)(1) after the word 'if' insert the words 'skilled medical services,'". The text of such section 2(f) does not provide sufficient amendatory instructions to execute an amendment. The apparent intent of the Congress was to amend section 395(a)(1) of the Public Health Service Act (42 U.S.C. 280c(a)(1)).

care services, homemaker or home health aide services, or personal care services are provided in the homes of the individuals;

(2) to pay the costs of the provision of such services in the homes of such individuals; and

(3) to coordinate the provision by public and private entities of such services, and other long-term care services, in the homes of such individuals.

(b) **REQUIREMENT WITH RESPECT TO AGE OF RECIPIENTS OF SERVICES.**—The Secretary may not make a grant under subsection (a) to a State unless the State agrees to ensure that—

(1) not less than 25 percent of the grant is expended to provide services under such subsection to individuals who are not less than 65 years of age; and

(2) of the portion of the grant reserved by the State for purposes of complying with paragraph (1), not less than 10 percent is expended to provide such services to individuals who are not less than 85 years of age.

(c) **RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.**—A State may not make payments from a grant under subsection (a) for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

SEC. 396. [280c-1] LIMITATION ON DURATION OF GRANT AND REQUIREMENT OF MATCHING FUNDS.

(a) **LIMITATION ON DURATION OF GRANT.**—The period during which payments are made to a State from a grant under section 395(a) may not exceed 3 years. Such payments shall be subject to annual evaluation by the Secretary.

(b) **REQUIREMENT OF MATCHING FUNDS.**—

(1)(A) For the first year of payments to a State from a grant under section 395(a), the Secretary may not make such payments in an amount exceeding 75 percent of the costs of services to be provided by the State pursuant to such section.

(B) For the second year of such payments to a State, the Secretary may not make such payments in an amount exceeding 65 percent of the costs of such services.

(C) For the third year of such payments to a State, the Secretary may not make such payments in an amount exceeding 55 percent of the costs of such services.

(2) The Secretary may not make a grant under section 395(a) to a State unless the State agrees to make available, directly or through donations from public or private entities, non-Federal contributions toward the costs of services to be provided pursuant to such section in an amount equal to—

(A) for the first year of payments to the State from the grant, not less than \$25 (in cash or in kind under subsection (c)) for each \$75 of Federal funds provided in the grant;

(B) for the second year of such payments to the State, not less than \$35 (in cash or in kind under subsection (c)) for each \$65 of such Federal funds; and

(C) for the third year of such payments to the State, not less than \$45 (in cash or in kind under subsection (c)) for each \$55 of such Federal funds.

(c) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—Non-Federal contributions required in subsection (b) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

SEC. 397. [280c-2] GENERAL PROVISIONS.

(a) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant under section 395(a) to a State unless the State agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(b) DESCRIPTION OF INTENDED USE OF GRANT.—The Secretary may not make a grant under section 395(a) to a State unless—

(1) the State submits to the Secretary a description of the purposes for which the State intends to expend the grant; and

(2) such description provides information relating to the programs and activities to be supported and services to be provided, including—

(A) the number of individuals who will receive services pursuant to section 395(a) and the average costs of providing such services to each such individual; and

(B) a description of the manner in which such programs and activities will be coordinated with any similar programs and activities of public and private entities.

(c) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under section 395(a) to a State unless the State has submitted to the Secretary an application for the grant. The application shall—

(1) contain the description of intended expenditures required in subsection (b);

(2) with respect to carrying out the purpose for which the grant is to be made, provide assurances of compliance satisfactory to the Secretary; and

(3) otherwise be in such form, be made in such manner, and contain such information and agreements as the Secretary determines to be necessary to carry out this subpart.

(d) EVALUATIONS AND REPORT BY SECRETARY.—The Secretary shall—

(1) provide for an evaluation of each demonstration project for which a grant is made under section 395(a); and

(2) not later than 6 months after the completion of such evaluations, submit to the Congress a report describing the findings made as a result of the evaluations.

(e) AUTHORIZATIONS OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated \$5,000,000 for each of the fiscal years 1988 through 1990,

\$7,500,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

Subpart II—Grants for Demonstrations Projects With Respect to Alzheimer's Disease

SEC. 398. [280c-3] ESTABLISHMENT OF PROGRAM.

(a) IN GENERAL.—The Secretary shall make not less than 5, and not more than 15, grants to States for the purpose of assisting grantees in carrying out demonstration projects for planning, establishing, and operating programs—

(1) to coordinate the development and operation with public and private organizations of diagnostic, treatment, care management, respite care, legal counseling, and education services provided within the State to individuals with Alzheimer's disease or related disorders and to the families and care providers of such individuals;

(2) to provide home health care, personal care, day care, companion services, short-term care in health facilities, and other respite care to individuals with Alzheimer's disease or related disorders; and

(3) to provide to health care providers, to individuals with Alzheimer's disease or related disorders, to the families of such individuals, to organizations established for such individuals and such families, and to the general public, information with respect to—

(A) diagnostic services, treatment services, and related services available to such individuals and to the families of such individuals;

(B) sources of assistance in obtaining such services, including assistance under entitlement programs; and

(C) the legal rights of such individuals and such families.

(b) REQUIREMENT WITH RESPECT TO CERTAIN EXPENDITURES.—The Secretary may not make a grant under subsection (a) to a State unless the State agrees to expend not less than 50 percent of the grant for the provision of services described in subsection (a)(2).

(c) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—A State may not make payments from a grant under subsection (a) for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

SEC. 398A. [280c-4] LIMITATION ON DURATION OF GRANT AND REQUIREMENT OF MATCHING FUNDS.

(a) LIMITATION ON DURATION OF GRANT.—The period during which payments are made to a State from a grant under section 398(a) may not exceed 3 years. Such payments shall be subject to annual evaluation by the Secretary.

(b) REQUIREMENT OF MATCHING FUNDS.—

(1)(A) For the first year of payments to a State from a grant under section 398(a), the Secretary may not make such payments in an amount exceeding 75 percent of the costs of services to be provided by the State pursuant to such section.

(B) For the second year of such payments to a State, the Secretary may not make such payments in an amount exceeding 65 percent of the costs of such services.

(C) For the third year of such payments to a State, the Secretary may not make such payments in an amount exceeding 55 percent of the costs of such services.

(2) The Secretary may not make a grant under section 398(a) to a State unless the State agrees to make available, directly or through donations from public or private entities, non-Federal contributions toward the costs of services to be provided pursuant to such section in an amount equal to—

(A) for the first year of payments to the State from the grant, not less than \$25 (in cash or in kind under subsection (c)) for each \$75 of Federal funds provided in the grant;

(B) for the second year of such payments to the State, not less than \$35 (in cash or in kind under subsection (c)) for each \$65 of such Federal funds; and

(C) for the third year of such payments to the State, not less than \$45 (in cash or in kind under subsection (c)) for each \$55 of such Federal funds.

(c) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—Non-Federal contributions required in subsection (b) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

SEC. 398B. [280c-5] GENERAL PROVISIONS.

(a) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant under section 398(a) to a State unless the State agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(b) DESCRIPTION OF INTENDED USE OF GRANT.—The Secretary may not make a grant under section 398(a) to a State unless—

(1) the State submits to the Secretary a description of the purposes for which the State intends to expend the grant; and

(2) such description provides information relating to the programs and activities to be supported and services to be provided, including—

(A) the number of individuals who will receive services pursuant to section 398(a) and the average costs of providing such services to each such individual; and

(B) a description of the manner in which such programs and activities will be coordinated with any similar programs and activities of public and private entities.

(c) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under section 398(a) to a State unless the State has

submitted to the Secretary an application for the grant. The application shall—

(1) contain the description of intended expenditures required in subsection (b);

(2) with respect to carrying out the purpose for which the grant is to be made, provide assurances of compliance satisfactory to the Secretary; and

(3) otherwise be in such form, be made in such manner, and contain such information and agreements as the Secretary determines to be necessary to carry out this subpart.

(d) EVALUATIONS AND REPORT BY SECRETARY.—The Secretary shall—

(1) provide for an evaluation of each demonstration project for which a grant is made under section 398(a); and

(2) not later than 6 months after the completion of such evaluations, submit to the Congress a report describing the findings made as a result of the evaluations.

(e) AUTHORIZATIONS OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated \$5,000,000 for each of the fiscal years 1988 through 1990, \$7,500,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

Subpart III—Grants for Home Visiting Services for At-Risk Families

SEC. 399. [280c-6] PROJECTS TO IMPROVE MATERNAL, INFANT, AND CHILD HEALTH.

(a) IN GENERAL.—

(1) ESTABLISHMENT OF PROGRAM.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make grants to eligible entities to pay the Federal share of the cost of providing the services specified in subsection (b) to families in which a member is—

(A) a pregnant woman at risk of delivering an infant with a health or developmental complication; or

(B) a child less than 3 years of age—

(i) who is experiencing or is at risk of a health or developmental complication, or of child abuse or neglect; or

(ii) who has been prenatally exposed to maternal substance abuse.

(2) MINIMUM PERIOD OF AWARDS; ADMINISTRATIVE CONSULTATIONS.—

(A) The Secretary shall award grants under paragraph

(1) for periods of at least three years.

(B) The Administrator of the Administration for Children, Youth, and Families and the Director of the National Commission to Prevent Infant Mortality shall be consulted regarding the promulgation of program guidelines and funding priorities under this section.

(3) REQUIREMENT OF STATUS AS MEDICAID PROVIDER.—

(A) Subject to subparagraph (B), the Secretary may make a grant under paragraph (1) only if, in the case of any service under such paragraph that is covered in the

State plan approved under title XIX of the Social Security Act for the State involved—

(i) the entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under paragraph (1), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(b) HOME VISITING SERVICES FOR ELIGIBLE FAMILIES.—With respect to an eligible family, each of the following services shall, directly or through arrangement with other public or nonprofit private entities, be available (as applicable to the family member involved) in each project operated with a grant under subsection (a):

(1) Prenatal and postnatal health care.

(2) Primary health care for the children, including developmental assessments.

(3) Education for the parents concerning infant care and child development, including the development and utilization of parent and teacher resource networks and other family resource and support networks where such networks are available.

(4) Upon the request of a parent, providing the education described in paragraph (3) to other individuals who have responsibility for caring for the children.

(5) Education for the parents concerning behaviors that adversely affect health.

(6) Assistance in obtaining necessary health, mental health, developmental, social, housing, and nutrition services and other assistance, including services and other assistance under maternal and child health programs; the special supplemental nutrition program for women, infants, and children; section 17 of the Child Nutrition Act of 1966; title V of the Social Security Act; title XIX of such Act (including the program for early and periodic screening, diagnostic, and treatment services described in section 1905(r) of such Act); titles IV and XIX of the Social Security Act; housing programs; other food

assistance programs; and appropriate alcohol and drug dependency treatment programs, according to need.

(c) CONSIDERATIONS IN MAKING GRANTS.—In awarding grants under subsection (a), the Secretary shall take into consideration—

(1) the ability of the entity involved to provide, either directly or through linkages, a broad range of preventive and primary health care services and related social, family support, and developmental services;

(2) different combinations of professional and lay home visitors utilized within programs that are reflective of the identified service needs and characteristics of target populations;

(3) the extent to which the population to be targeted has limited access to health care, and related social, family support, and developmental services; and

(4) whether such grants are equitably distributed among urban and rural settings and whether entities serving Native American communities are represented among the grantees.

(d) FEDERAL SHARE.—With respect to the costs of carrying out a project under subsection (a), a grant under such subsection for the project may not exceed 90 percent of such costs. To be eligible to receive such a grant, an applicant must provide assurances that the applicant will obtain at least 10 percent of such costs from non-Federal funds (and such contributions to such costs may be in cash or in-kind, including facilities and personnel).

(e) RULE OF CONSTRUCTION REGARDING AT-RISK BIRTHS.—For purposes of subsection (a)(1), a pregnant woman shall be considered to be at risk of delivering an infant with a health or developmental complication if during the pregnancy the woman—

(1) lacks appropriate access to, or information concerning, early and routine prenatal care;

(2) lacks the transportation necessary to gain access to the services described in subsection (b);

(3) lacks appropriate child care assistance, which results in impeding the ability of such woman to utilize health and related social services;

(4) is fearful of accessing substance abuse services or child and family support services; or

(5) is a minor with a low income.

(f) DELIVERY OF SERVICES AND CASE MANAGEMENT.—

(1) CASE MANAGEMENT MODEL.—Home visiting services provided under this section shall be delivered according to a case management model, and a registered nurse, licensed social worker, or other licensed health care professional with experience and expertise in providing health and related social services in home and community settings shall be assigned as the case manager for individual cases under such model.

(2) CASE MANAGER.—A case manager assigned under paragraph (1) shall have primary responsibility for coordinating and overseeing the development of a plan for each family that is to receive home visiting services under this section, and for coordinating the delivery of such services provided through appropriate personnel.

(3) **APPROPRIATE PERSONNEL.**—In determining which personnel shall be utilized in the delivery of services, the case manager shall consider—

(A) the stated objective of the project to be operated with the grant, as determined after considering identified gaps in the current service delivery system; and

(B) the nature of the needs of the family to be served, as determined at the initial assessment of the family that is conducted by the case manager, and through follow-up contacts by other providers of home visiting services.

(4) **FAMILY SERVICE PLAN.**—A case manager, in consultation with a team established in accordance with paragraph (5) for the family involved, shall develop a plan for the family following the initial visit to the home of the family. Such plan shall reflect—

(A) an assessment of the health and related social service needs of the family;

(B) a structured plan for the delivery of home visiting services to meet the identified needs of the family;

(C) the frequency with which such services are to be provided to the family;

(D) ongoing revisions made as the needs of family members change; and

(E) the continuing voluntary participation of the family in the plan.

(5) **HOME VISITING SERVICES TEAM.**—The team to be consulted under paragraph (4) on behalf of a family shall include, as appropriate, other nursing professionals, physician assistants, social workers, child welfare professionals, infant and early childhood specialists, nutritionists, and laypersons trained as home visitors. The case manager shall ensure that the plan is coordinated with those physician services that may be required by the mother or child.

(g) **OUTREACH.**—Each grantee under subsection (a) shall provide outreach and casefinding services to inform eligible families of the availability of home visiting services from the project.

(h) **CONFIDENTIALITY.**—In accordance with applicable State law, an entity receiving a grant under subsection (a) shall maintain confidentiality with respect to services provided to families under this section.

(i) **CERTAIN ASSURANCES.**—The Secretary may award a grant under subsection (a) only if the entity involved provides assurances satisfactory to the Secretary that—

(1) the entity will provide home visiting services with reasonable frequency—

(A) to families with pregnant women, as early in the pregnancy as is practicable, and until the infant reaches at least 2 years of age; and

(B) to other eligible families, for at least 2 years; and

(2) the entity will coordinate with public health and related social service agencies to prevent duplication of effort and improve the delivery of comprehensive health and related social services.

(j) **SUBMISSION TO SECRETARY OF CERTAIN INFORMATION.**—The Secretary may award a grant under subsection (a) only if the entity involved submits to the Secretary—

(1) a description of the population to be targeted for home visiting services and methods of outreach and casefinding for identifying eligible families, including the use of lay home visitors where appropriate;

(2) a description of the types and qualifications of home visitors used by the entity and the process by which the entity will provide continuing training and sufficient support to the home visitors; and

(3) such other information as the Secretary determines to be appropriate.

(k) **LIMITATION REGARDING ADMINISTRATIVE EXPENSES.**—Not more than 10 percent of a grant under subsection (a) may be expended for administrative expenses with respect to the grant. The costs of training individuals to serve in the project involved are not subject to the preceding sentence.

(l) **RESTRICTIONS ON USE OF GRANT.**—To be eligible to receive a grant under this section, an entity must agree that the grant will not be expended—

(1) to provide inpatient hospital services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(m) **REPORTS TO SECRETARY.**—To be eligible to receive a grant under this section, an entity must agree to submit an annual report on the services provided under this section to the Secretary in such manner and containing such information as the Secretary by regulation requires. At a minimum, the entity shall report information concerning eligible families, including—

(1) the characteristics of the families and children receiving services under this section;

(2) the usage, nature, and location of the provider, of preventive health services, including prenatal, primary infant, and child health care;

(3) the incidence of low birthweight and premature infants;

(4) the length of hospital stays for pre- and post-partum women and their children;

(5) the incidence of substantiated child abuse and neglect for all children within participating families;

(6) the number of emergency room visits for routine health care;

(7) the source of payment for health care services and the extent to which the utilization of health care services, other than routine screening and medical care, available to the individuals under the program established under title XIX of the

Social Security Act, and under other Federal, State, and local programs, is reduced;

(8) the number and type of referrals made for health and related social services, including alcohol and drug treatment services, and the utilization of such services provided by the grantee; and

(9) the incidence of developmental disabilities.

(n) REQUIREMENT OF APPLICATION.—The Secretary may make a grant under subsection (a) only if—

(1) an application for the grant is submitted to the Secretary;

(2) the application contains the agreements and assurances required in this section, and the information required in subsection (j);

(3) the application contains evidence that the preparation of the application has been coordinated with the State agencies responsible for maternal and child health and child welfare, and coordinated with services provided under part H of the Individuals with Disabilities Education Act; and

(4) the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(o) PEER REVIEW.—

(1) REQUIREMENT.—In making determinations for awarding grants under subsection (a), the Secretary shall rely on the recommendations of the peer review panel established under paragraph (2).

(2) COMPOSITION.—The Secretary shall establish a review panel to make recommendations under paragraph (1) that shall be composed of—

(A) national experts in the fields of maternal and child health, child abuse and neglect, and the provision of community-based primary health services; and

(B) representatives of relevant Federal agencies, including the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Administration for Children, Youth, and Families, the U.S. Advisory Board on Child Abuse and Neglect, and the National Commission to Prevent Infant Mortality.

(p) EVALUATIONS.—

(1) IN GENERAL.—The Secretary shall, directly or through contracts with public or private entities—

(A) conduct evaluations to determine the effectiveness of projects under subsection (a) in reducing the incidence of children born with health or developmental complications, the incidence among children less than 3 years of age of such complications, and the incidence of child abuse and neglect; and

(B) not less than once during each 3-year period, prepare and submit to the appropriate committees of Congress a report concerning the results of such evaluations.

(2) CONTENTS.—The evaluations conducted under paragraph (1) shall—

(A) include a summary of the data contained in the annual reports submitted under subsection (m);

(B) assess the relative effectiveness of projects under subsection (a) in urban and rural areas, and among programs utilizing differing combinations of professionals and trained home visitors recruited from the community to meet the needs of defined target service populations; and

(C) make further recommendations necessary or desirable to increase the effectiveness of such projects.

(q) DEFINITIONS.—For purposes of this section:

(1) The term “eligible entity” includes public and nonprofit private entities that provide health or related social services, including community-based organizations, visiting nurse organizations, hospitals, local health departments, community health centers, Native Hawaiian health centers, nurse managed clinics, family service agencies, child welfare agencies, developmental service providers, family resource and support programs, and resource mothers projects.

(2) The term “eligible family” means a family described in subsection (a).

(3) The term “health or developmental complication”, with respect to a child, means—

(A) being born in an unhealthy or potentially unhealthy condition, including premature birth, low birthweight, and prenatal exposure to maternal substance abuse;

(B) a condition arising from a condition described in subparagraph (A);

(C) a physical disability or delay; and

(D) a developmental disability or delay.

(4) The term “home visiting services” means the services specified in subsection (b), provided at the residence of the eligible family involved or provided pursuant to arrangements made for the family (including arrangements for services in community settings).

(5) The term “home visitors” means providers of home visiting services.

(r) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$30,000,000 for each of the fiscal years 1993 and 1994.

PART L—SERVICES FOR CHILDREN OF SUBSTANCE ABUSERS

SEC. 399D. [280d] GRANTS FOR SERVICES FOR CHILDREN OF SUBSTANCE ABUSERS.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make grants to public and nonprofit private entities for the purpose of carrying out programs—

(A) to provide the services described in subsection (b) to children of substance abusers;

(B) to provide the applicable services described in subsection (c) to families in which a member is a substance abuser; and

(C) to identify such children and such families.

(2) ADMINISTRATIVE CONSULTATIONS.—The Administrator of the Administration for Children, Youth, and Families and the Administrator of the Substance Abuse and Mental Health Services Administration shall be consulted regarding the promulgation of program guidelines and funding priorities under this section.

(3) REQUIREMENT OF STATUS AS MEDICAID PROVIDER.—

(A) Subject to subparagraph (B), the Secretary may make a grant under paragraph (1) only if, in the case of any service under such paragraph that is covered in the State plan approved under title XIX of the Social Security Act for the State involved—

(i) the entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under paragraph (1), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(b) SERVICES FOR CHILDREN OF SUBSTANCE ABUSERS.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees to make available (directly or through agreements with other entities) to children of substance abusers each of the following services:

(1) Periodic evaluation of children for developmental, psychological, and medical problems.

(2) Primary pediatric care.

(3) Other necessary health and mental health services.

(4) Therapeutic intervention services for children, including provision of therapeutic child care.

(5) Preventive counseling services.

(6) Counseling related to the witnessing of chronic violence.

(7) Referrals for, and assistance in establishing eligibility for, services provided under—

(A) education and special education programs;

(B) Head Start programs established under the Head Start Act;

(C) other early childhood programs;

(D) employment and training programs;

(E) public assistance programs provided by Federal, State, or local governments; and

(F) programs offered by vocational rehabilitation agencies, recreation departments, and housing agencies.

(8) Additional developmental services that are consistent with the provision of early intervention services, as such term is defined in part H of the Individuals with Disabilities Education Act.

(c) SERVICES FOR AFFECTED FAMILIES.—The Secretary may make a grant under subsection (a) only if, in the case of families in which a member is a substance abuser, the applicant involved agrees to make available (directly or through agreements with other entities) each of the following services, as applicable to the family member involved:

(1) Services as follows, to be provided by a public health nurse, social worker, or similar professional, or by a trained worker from the community who is supervised by a professional:

(A) Counseling to substance abusers on the benefits and availability of substance abuse treatment services and services for children of substance abusers.

(B) Assistance to substance abusers in obtaining and using substance abuse treatment services and in obtaining the services described in subsection (b) for their children.

(C) Visiting and providing support to substance abusers, especially pregnant women, who are receiving substance abuse treatment services or whose children are receiving services under subsection (b).

(2) In the case of substance abusers:

(A) Encouragement and, where necessary, referrals to participate in appropriate substance abuse treatment.

(B) Primary health care and mental health services, including prenatal and post partum care for pregnant women.

(C) Consultation and referral regarding subsequent pregnancies and life options, including education and career planning.

(D) Where appropriate, counseling regarding family conflict and violence.

(E) Remedial education services.

(F) Referrals for, and assistance in establishing eligibility for, services described in subsection (b)(7).

(3) In the case of substance abusers, spouses of substance abusers, extended family members of substance abusers, caretakers of children of substance abusers, and other people significantly involved in the lives of substance abusers or the children of substance abusers:

(A) An assessment of the strengths and service needs of the family and the assignment of a case manager who will coordinate services for the family.

(B) Therapeutic intervention services, such as parental counseling, joint counseling sessions for families and children, and family therapy.

(C) Child care or other care for the child to enable the parent to attend treatment or other activities and respite care services.

(D) Parenting education services and parent support groups.

(E) Support services, including, where appropriate, transportation services.

(F) Where appropriate, referral of other family members to related services such as job training.

(G) Aftercare services, including continued support through parent groups and home visits.

(d) CONSIDERATIONS IN MAKING GRANTS.—In making grants under subsection (a), the Secretary shall ensure that the grants are reasonably distributed among the following types of entities:

(1) Alcohol and drug treatment programs, especially those providing treatment to pregnant women and mothers and their children.

(2) Public or nonprofit private entities that provide health or social services to disadvantaged populations, and that have—

(A) expertise in applying the services to the particular problems of substance abusers and the children of substance abusers; and

(B) an affiliation or contractual relationship with one or more substance abuse treatment programs.

(3) Consortia of public or nonprofit private entities that include at least one substance abuse treatment program.

(4) Indian tribes.

(e) FEDERAL SHARE.—The Federal share of a program carried out under subsection (a) shall be 90 percent. The Secretary shall accept the value of in-kind contributions, including facilities and personnel, made by the grant recipient as a part or all of the non-Federal share of grants.

(f) COORDINATION WITH OTHER PROVIDERS.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees to coordinate its activities with those of the State lead agency, and the State Interagency Coordinating Council, under part H of the Individuals with Disabilities Education Act.

(g) RESTRICTIONS ON USE OF GRANT.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that the grant will not be expended—

(1) to provide inpatient hospital services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(h) SUBMISSION TO SECRETARY OF CERTAIN INFORMATION.—The Secretary may make a grant under subsection (a) only if the applicant involved submits to the Secretary—

(1) a description of the population that is to receive services under this section and a description of such services that are to be provided and measurable goals and objectives;

(2) a description of the mechanism that will be used to involve the local public agencies responsible for health, mental health, child welfare, education, juvenile justice, developmental disabilities, and substance abuse treatment programs in planning and providing services under this section, as well as evidence that the proposal has been coordinated with the State agencies responsible for administering those programs and the State agency responsible for administering public maternal and child health services;

(3) information demonstrating that the applicant has established a collaborative relationship with child welfare agencies and child protective services that will enable the applicant, where appropriate, to—

(A) provide advocacy on behalf of substance abusers and the children of substance abusers in child protective services cases;

(B) provide services to help prevent the unnecessary placement of children in substitute care; and

(C) promote reunification of families or permanent plans for the placement of the child; and

(4) such other information as the Secretary determines to be appropriate.

(i) REPORTS TO SECRETARY.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that for each fiscal year for which the applicant receives such a grant the applicant, in accordance with uniform standards developed by the Secretary, will submit to the Secretary a report containing—

(1) a description of specific services and activities provided under the grant;

(2) information regarding progress toward meeting the program's stated goals and objectives;

(3) information concerning the extent of use of services provided under the grant, including the number of referrals to related services and information on other programs or services accessed by children, parents, and other caretakers;

(4) information concerning the extent to which parents were able to access and receive treatment for alcohol and drug abuse and sustain participation in treatment over time until the provider and the individual receiving treatment agree to end such treatment, and the extent to which parents re-enter treatment after the successful or unsuccessful termination of treatment;

(5) information concerning the costs of the services provided and the source of financing for health care services;

(6) information concerning—

(A) the number and characteristics of families, parents, and children served, including a description of the type and severity of childhood disabilities, and an analysis of the number of children served by age;

(B) the number of children served who remained with their parents during the period in which entities provided services under this section;

(C) the number of children served who were placed in out-of-home care during the period in which entities provided services under this section;

(D) the number of children described in subparagraph (C) who were reunited with their families; and

(E) the number of children described in subparagraph (C) for whom a permanent plan has not been made or for whom the permanent plan is other than family reunification;

(7) information on hospitalization or emergency room use by the family members participating in the program; and

(8) such other information as the Secretary determines to be appropriate.

(j) REQUIREMENT OF APPLICATION.—The Secretary may make any grant under subsection (a) only if—

(1) an application for the grant is submitted to the Secretary;

(2) the application contains the agreements required in this section and the information required in subsection (h); and

(3) the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(k) PEER REVIEW.—

(1) REQUIREMENT.—In making determinations for awarding grants under subsection (a), the Secretary shall rely on the recommendations of the peer review panel established under paragraph (2).

(2) COMPOSITION.—The Secretary shall establish a review panel to make recommendations under paragraph (1) that shall be composed of—

(A) national experts in the fields of maternal and child health, substance abuse treatment, and child welfare; and

(B) representatives of relevant Federal agencies, including the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, and the Administration for Children, Youth, and Families.

(l) EVALUATIONS.—The Secretary shall periodically conduct evaluations to determine the effectiveness of programs supported under subsection (a)—

(1) in reducing the incidence of alcohol and drug abuse among substance abusers participating in the programs;

(2) in preventing adverse health conditions in children of substance abusers;

(3) in promoting better utilization of health and developmental services and improving the health, developmental,

and psychological status of children receiving services under the program;

(4) in improving parental and family functioning;

(5) in reducing the incidence of out-of-home placement for children whose parents receive services under the program; and

(6) in facilitating the reunification of families after children have been placed in out-of-home care.

(m) REPORT TO CONGRESS.—Not later than 2 years after the date on which amounts are first appropriated under subsection (o), the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report that contains a description of programs carried out under this section. At a minimum, the report shall contain—

(1) information concerning the number and type of programs receiving grants;

(2) information concerning the type and use of services offered;

(3) information concerning—

(A) the number and characteristics of families, parents, and children served;

(B) the number of children served who remained with their parents during or after the period in which entities provided services under this section;

(C) the number of children served who were placed in out-of-home care during the period in which entities provided services under this section;

(D) the number of children described in subparagraph (C) who were reunited with their families; and

(E) the number of children described in subparagraph (C) who were permanently placed in out-of-home care; analyzed by the type of entity described in subsection (d) that provided services;

(4) an analysis of the access provided to, and use of, related services and alcohol and drug treatment through programs carried out under this section; and

(5) a comparison of the costs of providing services through each of the types of entities described in subsection (d).

(n) DATA COLLECTION.—The Secretary shall periodically collect and report on information concerning the numbers of children in substance abusing families, including information on the age, gender and ethnicity of the children, the composition and income of the family, and the source of health care finances.

(o) DEFINITIONS.—For purposes of this section:

(1) The term “caretaker”, with respect to a child of a substance abuser, means any individual acting in a parental role regarding the child (including any birth parent, foster parent, adoptive parent, relative of such a child, or other individual acting in such a role).

(2) The term “children of substance abusers” means—

(A) children who have lived or are living in a household with a substance abuser who is acting in a parental role regarding the children; and

(B) children who have been prenatally exposed to alcohol or other dangerous drugs.

(3) The term "Indian tribe" means any tribe, band, nation, or other organized group or community of Indians, including any Alaska Native village (as defined in, or established pursuant to, the Alaska Native Claims Settlement Act), that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(4) The term "public or nonprofit private entities that provide health or social services to disadvantaged populations" includes community-based organizations, local public health departments, community action agencies, hospitals, community health centers, child welfare agencies, developmental disabilities service providers, and family resource and support programs.

(5) The term "substance abuse" means the abuse of alcohol or other drugs.

(p) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$50,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(2) CONTINGENT AUTHORITY REGARDING TRAINING OF CERTAIN INDIVIDUALS.—Of the amounts appropriated under paragraph (1) for a fiscal year in excess of \$25,000,000, the Secretary may make available not more than 15 percent for the training of health care professionals and other personnel (including child welfare providers) who provide services to children and families of substance abusers.

PART M—NATIONAL PROGRAM OF CANCER REGISTRIES

SEC. 399H. [280e] NATIONAL PROGRAM OF CANCER REGISTRIES.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States, or may make grants or enter into contracts with academic or nonprofit organizations designated by the State to operate the State's cancer registry in lieu of making a grant directly to the State, to support the operation of population-based, statewide cancer registries in order to collect, for each form of in-situ and invasive cancer (with the exception of basal cell and squamous cell carcinoma of the skin), data concerning—

(1) demographic information about each case of cancer;

(2) information on the industrial or occupational history of the individuals with the cancers, to the extent such information is available from the same record;

(3) administrative information, including date of diagnosis and source of information;

(4) pathological data characterizing the cancer, including the cancer site, stage of disease (pursuant to Staging Guide), incidence, and type of treatment; and

(5) other elements determined appropriate by the Secretary.

(b) MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may make a grant under subsection (a) only if the State, or the academic or nonprofit private organization designated by the State to operate the cancer registry of the State, involved agrees, with respect to the costs of the program, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs or \$1 for every \$3 of Federal funds provided in the grant.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION; MAINTENANCE OF EFFORT.—

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) With respect to a State in which the purpose described in subsection (a) is to be carried out, the Secretary, in making a determination of the amount of non-Federal contributions provided under paragraph (1), may include only such contributions as are in excess of the amount of such contributions made by the State toward the collection of data on cancer for the fiscal year preceding the first year for which a grant under subsection (a) is made with respect to the State. The Secretary may decrease the amount of non-Federal contributions that otherwise would have been required by this subsection in those cases in which the State can demonstrate that decreasing such amount is appropriate because of financial hardship.

(c) ELIGIBILITY FOR GRANTS.—

(1) IN GENERAL.—No grant shall be made by the Secretary under subsection (a) unless an application has been submitted to, and approved by, the Secretary. Such application shall be in such form, submitted in such a manner, and be accompanied by such information, as the Secretary may specify. No such application may be approved unless it contains assurances that the applicant will use the funds provided only for the purposes specified in the approved application and in accordance with the requirements of this section, that the application will establish such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement and accounting of Federal funds paid to the applicant under subsection (a) of this section, and that the applicant will comply with the peer review requirements under sections 491 and 492.

(2) ASSURANCES.—Each applicant, prior to receiving Federal funds under subsection (a), shall provide assurances satisfactory to the Secretary that the applicant will—

(A) provide for the establishment of a registry in accordance with subsection (a);

(B) comply with appropriate standards of completeness, timeliness, and quality of population-based cancer registry data;

(C) provide for the annual publication of reports of cancer data under subsection (a); and

(D) provide for the authorization under State law of the statewide cancer registry, including promulgation of regulations providing—

(i) a means to assure complete reporting of cancer cases (as described in subsection (a)) to the statewide cancer registry by hospitals or other facilities providing screening, diagnostic or therapeutic services to patients with respect to cancer;

(ii) a means to assure the complete reporting of cancer cases (as defined in subsection (a)) to the statewide cancer registry by physicians, surgeons, and all other health care practitioners diagnosing or providing treatment for cancer patients, except for cases directly referred to or previously admitted to a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that State and reported by those facilities;

(iii) a means for the statewide cancer registry to access all records of physicians and surgeons, hospitals, outpatient clinics, nursing homes, and all other facilities, individuals, or agencies providing such services to patients which would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer, or medical status of any identified patient;

(iv) for the reporting of cancer case data to the statewide cancer registry in such a format, with such data elements, and in accordance with such standards of quality timeliness and completeness, as may be established by the Secretary;

(v) for the protection of the confidentiality of all cancer case data reported to the statewide cancer registry, including a prohibition on disclosure to any person of information reported to the statewide cancer registry that identifies, or could lead to the identification of, an individual cancer patient, except for disclosure to other State cancer registries and local and State health officers;

(vi) for a means by which confidential case data may in accordance with State law be disclosed to cancer researchers for the purposes of cancer prevention, control and research;

(vii) for the authorization or the conduct, by the statewide cancer registry or other persons and organizations, of studies utilizing statewide cancer registry data, including studies of the sources and causes of cancer, evaluations of the cost, quality, efficacy, and appropriateness of diagnostic, therapeutic, rehabilitative, and preventative services and programs relating

to cancer, and any other clinical, epidemiological, or other cancer research; and

(viii) for protection for individuals complying with the law, including provisions specifying that no person shall be held liable in any civil action with respect to a cancer case report provided to the statewide cancer registry, or with respect to access to cancer case information provided to the statewide cancer registry.

(d) RELATIONSHIP TO CERTAIN PROGRAMS.—

(1) **IN GENERAL.**—This section may not be construed to act as a replacement for or diminishment of the program carried out by the Director of the National Cancer Institute and designated by such Director as the Surveillance, Epidemiology, and End Results Program (SEER).

(2) **SUPPLANTING OF ACTIVITIES.**—In areas where both such programs exist, the Secretary shall ensure that SEER support is not supplanted and that any additional activities are consistent with the guidelines provided for in subsection (c)(2) (C) and (D) and are appropriately coordinated with the existing SEER program.

(3) **TRANSFER OF RESPONSIBILITY.**—The Secretary may not transfer administration responsibility for such SEER program from such Director.

(4) **COORDINATION.**—To encourage the greatest possible efficiency and effectiveness of Federally supported efforts with respect to the activities described in this subsection, the Secretary shall take steps to assure the appropriate coordination of programs supported under this part with existing Federally supported cancer registry programs.

(e) **REQUIREMENT REGARDING CERTAIN STUDY ON BREAST CANCER.**—In the case of a grant under subsection (a) to any State specified in section 399K(b), the Secretary may establish such conditions regarding the receipt of the grant as the Secretary determines are necessary to facilitate the collection of data for the study carried out under section 399C.

SEC. 399I. [280e-1] PLANNING GRANTS REGARDING REGISTRIES.

(a) IN GENERAL.—

(1) **STATES.**—The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States for the purpose of developing plans that meet the assurances required by the Secretary under section 399B(c)(2).

(2) **OTHER ENTITIES.**—For the purpose described in paragraph (1), the Secretary may make grants to public entities other than States and to nonprofit private entities. Such a grant may be made to an entity only if the State in which the purpose is to be carried out has certified that the State approves the entity as qualified to carry out the purpose.

(b) **APPLICATION.**—The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary, the application contains the certification required in subsection (a)(2) (if the application is for a grant under such subsection), and the application is in such form, is made in such man-

ner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

SEC. 399J. [280e-2] TECHNICAL ASSISTANCE IN OPERATIONS OF STATEWIDE CANCER REGISTRIES.

The Secretary, acting through the Director of the Centers for Disease Control, may, directly or through grants and contracts, or both, provide technical assistance to the States in the establishment and operation of statewide registries, including assistance in the development of model legislation for statewide cancer registries and assistance in establishing a computerized reporting and data processing system.

SEC. 399K. [280e-3] STUDY IN CERTAIN STATES TO DETERMINE THE FACTORS CONTRIBUTING TO THE ELEVATED BREAST CANCER MORTALITY RATES.

(a) **IN GENERAL.**—Subject to subsections (c) and (d), the Secretary, acting through the Director of the National Cancer Institute, shall conduct a study for the purpose of determining the factors contributing to the fact that breast cancer mortality rates in the States specified in subsection (b) are elevated compared to rates in other States.

(b) **RELEVANT STATES.**—The States referred to in subsection (a) are Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, and the District of Columbia.

(c) **COOPERATION OF STATE.**—The Secretary may conduct the study required in subsection (a) in a State only if the State agrees to cooperate with the Secretary in the conduct of the study, including providing information from any registry operated by the State pursuant to section 399H(a).

(d) **PLANNING, COMMENCEMENT, AND DURATION.**—The Secretary shall, during each of the fiscal years 1993 and 1994, develop a plan for conducting the study required in subsection (a). The study shall be initiated by the Secretary not later than fiscal year 1994, and the collection of data under the study may continue through fiscal year 1998.

(e) **REPORT.**—Not later than September 30, 1999, the Secretary shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings and recommendations made as a result of the study.

SEC. 399L. [280e-4] AUTHORIZATION OF APPROPRIATIONS.

(a) **REGISTRIES.**—For the purpose of carrying out this part, there are authorized to be appropriated \$30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998. Of the amounts appropriated under the preceding sentence for any such fiscal year, the Secretary may obligate not more than 25 percent for carrying out section 399I, and not more than 10 percent may be expended for assessing the accuracy, completeness and quality of data collected, and not more than 10 percent of which is to be expended under subsection 399J.

(b) **BREAST CANCER STUDY.**—Of the amounts appropriated for the National Cancer Institute under subpart 1 of part C of title IV

for any fiscal year in which the study required in section 399K is being carried out, the Secretary shall expend not less than \$1,000,000 for the study.

PART N—NATIONAL FOUNDATION FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION

SEC. 399F.¹ [280d-11] ESTABLISHMENT AND DUTIES OF FOUNDATION.

(a) **IN GENERAL.**—There shall be established in accordance with this section a nonprofit private corporation to be known as the National Foundation for the Centers for Disease Control and Prevention (in this part referred to as the "Foundation"). The Foundation shall not be an agency or instrumentality of the Federal Government, and officers, employees, and members of the board of the Foundation shall not be officers or employees of the Federal Government.

(b) **PURPOSE OF FOUNDATION.**—The purpose of the Foundation shall be to support and carry out activities for the prevention and control of diseases, disorders, injuries, and disabilities, and for promotion of public health.

(c) **ENDOWMENT FUND.**—

(1) **IN GENERAL.**—In carrying out subsection (b), the Foundation shall establish a fund for providing endowments for positions that are associated with the Centers for Disease Control and Prevention and dedicated to the purpose described in such subsection. Subject to subsection (f)(1)(B), the fund shall consist of such donations as may be provided by non-Federal entities and such non-Federal assets of the Foundation (including earnings of the Foundation and the fund) as the Foundation may elect to transfer to the fund.

(2) **AUTHORIZED EXPENDITURES OF FUND.**—The provision of endowments under paragraph (1) shall be the exclusive function of the fund established under such paragraph. Such endowments may be expended only for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the positions, and for recruiting individuals to hold the positions endowed by the fund.

(d) **CERTAIN ACTIVITIES OF FOUNDATION.**—In carrying out subsection (b), the Foundation may provide for the following with respect to the purpose described in such subsection:

(1) Programs of fellowships for State and local public health officials to work and study in association with the Centers for Disease Control and Prevention.

(2) Programs of international arrangements to provide opportunities for public health officials of other countries to serve in public health capacities in the United States in association with the Centers for Disease Control and Prevention or elsewhere, or opportunities for employees of such Centers (or other public health officials in the United States) to serve in such capacities in other countries, or both.

¹ So in law. See 201 of Public Law 102-531 (106 Stat. 3474). Part N begins with section 399F.

(3) Studies, projects, and research (which may include applied research on the effectiveness of prevention activities, demonstration projects, and programs and projects involving international, Federal, State, and local governments).

(4) Forums for government officials and appropriate private entities to exchange information. Participants in such forums may include institutions of higher education and appropriate international organizations.

(5) Meetings, conferences, courses, and training workshops.

(6) Programs to improve the collection and analysis of data on the health status of various populations.

(7) Programs for writing, editing, printing, and publishing of books and other materials.

(8) Other activities to carry out the purpose described in subsection (b).

(e) GENERAL STRUCTURE OF FOUNDATION; NONPROFIT STATUS.—

(1) BOARD OF DIRECTORS.—The Foundation shall have a board of directors (in this part referred to as the "Board"), which shall be established and conducted in accordance with subsection (f). The Board shall establish the general policies of the Foundation for carrying out subsection (b), including the establishment of the bylaws of the Foundation.

(2) EXECUTIVE DIRECTOR.—The Foundation shall have an executive director (in this part referred to as the "Director"), who shall be appointed by the Board, who shall serve at the pleasure of the Board, and for whom the Board shall establish the rate of compensation. Subject to compliance with the policies and bylaws established by the Board pursuant to paragraph (1), the Director shall be responsible for the daily operations of the Foundation in carrying out subsection (b).

(3) NONPROFIT STATUS.—In carrying out subsection (b), the Board shall establish such policies and bylaws under paragraph (1), and the Director shall carry out such activities under paragraph (2), as may be necessary to ensure that the Foundation maintains status as an organization that—

(A) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986; and

(B) is, under subsection (a) of such section, exempt from taxation.

(f) BOARD OF DIRECTORS.—

(1) CERTAIN BYLAWS.—

(A) In establishing bylaws under subsection (e)(1), the Board shall ensure that the bylaws of the Foundation include bylaws for the following:

(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

(ii) Policies, including ethical standards, for the acceptance and disposition of donations to the Foundation and for the disposition of the assets of the Foundation.

(iii) Policies for the conduct of the general operations of the Foundation.

(iv) Policies for writing, editing, printing, and publishing of books and other materials, and the acquisition of patents and licenses for devices and procedures developed by the Foundation.

(B) In establishing bylaws under subsection (e)(1), the Board shall ensure that the bylaws of the Foundation (and activities carried out under the bylaws) do not—

(i) reflect unfavorably upon the ability of the Foundation, or the Centers for Disease Control and Prevention, to carry out its responsibilities or official duties in a fair and objective manner; or

(ii) compromise, or appear to compromise, the integrity of any governmental program or any officer or employee involved in such program.

(2) COMPOSITION.—

(A) Subject to subparagraph (B), the Board shall be composed of 7 individuals, appointed in accordance with paragraph (4), who collectively possess education or experience appropriate for representing the general field of public health, the general field of international health, and the general public. Each such individual shall be a voting member of the Board.

(B) The Board may, through amendments to the bylaws of the Foundation, provide that the number of members of the Board shall be a greater number than the number specified in subparagraph (A).

(3) CHAIR.—The Board shall, from among the members of the Board, designate an individual to serve as the chair of the Board (in this subsection referred to as the “Chair”).

(4) APPOINTMENTS, VACANCIES, AND TERMS.—Subject to subsection (j) (regarding the initial membership of the Board), the following shall apply to the Board:

(A) Any vacancy in the membership of the Board shall be filled by appointment by the Board, after consideration of suggestions made by the Chair and the Director regarding the appointments. Any such vacancy shall be filled not later than the expiration of the 180-day period beginning on the date on which the vacancy occurs.

(B) The term of office of each member of the Board appointed under subparagraph (A) shall be 5 years. A member of the Board may continue to serve after the expiration of the term of the member until the expiration of the 180-day period beginning on the date on which the term of the member expires.

(C) A vacancy in the membership of the Board shall not affect the power of the Board to carry out the duties of the Board. If a member of the Board does not serve the full term applicable under subparagraph (B), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(5) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. The members may

be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board.

(g) CERTAIN RESPONSIBILITIES OF EXECUTIVE DIRECTOR.—In carrying out subsection (e)(2), the Director shall carry out the following functions:

(1) Hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees.

(2) Accept and administer donations to the Foundation, and administer the assets of the Foundation.

(3) Establish a process for the selection of candidates for holding endowed positions under subsection (c).

(4) Enter into such financial agreements as are appropriate in carrying out the activities of the Foundation.

(5) Take such action as may be necessary to acquire patents and licenses for devices and procedures developed by the Foundation and the employees of the Foundation.

(6) Adopt, alter, and use a corporate seal, which shall be judicially noticed.

(7) Commence and respond to judicial proceedings in the name of the Foundation.

(8) Other functions that are appropriate in the determination of the Director.

(h) GENERAL PROVISIONS.—

(1) AUTHORITY FOR ACCEPTING FUNDS.—The Director of the Centers for Disease Control and Prevention may accept and utilize, on behalf of the Federal Government, any gift, donation, bequest, or devise of real or personal property from the Foundation for the purpose of aiding or facilitating the work of such Centers. Funds may be accepted and utilized by such Director under the preceding sentence without regard to whether the funds are designated as general-purpose funds or special-purpose funds.

(2) AUTHORITY FOR ACCEPTANCE OF VOLUNTARY SERVICES.—

(A) The Director of the Centers for Disease Control and Prevention may accept, on behalf of the Federal Government, any voluntary services provided to such Centers by the Foundation for the purpose of aiding or facilitating the work of such Centers. In the case of an individual, such Director may accept the services provided under the preceding sentence by the individual for not more than 2 years.

(B) The limitation established in subparagraph (A) regarding the period of time in which services may be accepted applies to each individual who is not an employee of the Federal Government and who serves in association with the Centers for Disease Control and Prevention pursuant to financial support from the Foundation.

(3) ADMINISTRATIVE CONTROL.—No officer, employee, or member of the Board of the Foundation may exercise any administrative or managerial control over any Federal employee.

(4) APPLICABILITY OF CERTAIN STANDARDS TO NON-FEDERAL EMPLOYEES.—In the case of any individual who is not an em-

ployee of the Federal Government and who serves in association with the Centers for Disease Control and Prevention pursuant to financial support from the Foundation, the Foundation shall negotiate a memorandum of understanding with the individual and the Director of the Centers for Disease Control and Prevention specifying that the individual—

(A) shall be subject to the ethical and procedural standards regulating Federal employment, scientific investigation, and research findings (including publications and patents) that are required of individuals employed by the Centers for Disease Control and Prevention, including standards under this Act, the Ethics in Government Act, and the Technology Transfer Act; and

(B) shall be subject to such ethical and procedural standards under chapter 11 of title 18, United States Code (relating to conflicts of interest), as the Director of such Centers determines is appropriate, except such memorandum may not provide that the individual shall be subject to the standards of section 209 of such chapter.

(5) FINANCIAL CONFLICTS OF INTEREST.—Any individual who is an officer, employee, or member of the Board of the Foundation may not directly or indirectly participate in the consideration or determination by the Foundation of any question affecting—

(A) any direct or indirect financial interest of the individual; or

(B) any direct or indirect financial interest of any business organization or other entity of which the individual is an officer or employee or in which the individual has a direct or indirect financial interest.

(6) AUDITS; AVAILABILITY OF RECORDS.—The Foundation shall—

(A) provide for biennial audits of the financial condition of the Foundation; and

(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

(7) REPORTS.—

(A) Not later than February 1 of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation.

(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts to the Foundation of real or personal property, and the source and amount of all gifts to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts to the Foundation may be used.

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available for public in-

spection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

(8) **LIAISON FROM CENTERS FOR DISEASE CONTROL AND PREVENTION.**—The Director of the Centers for Disease Control and Prevention shall serve as the liaison representative of such Centers to the Board and the Foundation.

(i) **FEDERAL FUNDING.**—

(1) **AUTHORITY FOR ANNUAL GRANTS.**—

(A) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(i) for fiscal year 1993, make a grant to an entity described in subsection (j)(9) (relating to the establishment of a committee to establish the Foundation);

(ii) for fiscal year 1994, make a grant to the committee established under such subsection, or if the Foundation has been established, to the Foundation; and

(iii) for fiscal year 1995 and each subsequent fiscal year, make a grant to the Foundation.

(B) A grant under subparagraph (A) may be expended—

(i) in the case of an entity receiving the grant under subparagraph (A)(i), only for the purpose of carrying out the duties established in subsection (j)(9) for the entity;

(ii) in the case of the committee established under such subsection, only for the purpose of carrying out the duties established in subsection (j) for the committee; and

(iii) in the case of the Foundation, only for the purpose of the administrative expenses of the Foundation.

(C) A grant under subparagraph (A) may not be expended to provide amounts for the fund established under subsection (c).

(D) For the purposes described in subparagraph (B)—

(i) any portion of the grant made under subparagraph (A)(i) for fiscal year 1993 that remains unobligated after the entity receiving the grant completes the duties established in subsection (j)(9) for the entity shall be available to the committee established under such subsection; and

(ii) any portion of a grant under subparagraph (A) made for fiscal year 1993 or 1994 that remains unobligated after such committee completes the duties established in such subsection for the committee shall be available to the Foundation.

(2) **FUNDING FOR GRANTS.**—

(A) For the purpose of grants under paragraph (1), there is authorized to be appropriated \$500,000 for each fiscal year.

(B) For the purpose of grants under paragraph (1), the Secretary may for each fiscal year make available not

more than \$500,000 from the amounts appropriated for the fiscal year for the programs of the Department of Health and Human Services. Such amounts may be made available without regard to whether amounts have been appropriated under subparagraph (A).

(3) CERTAIN RESTRICTION.—If the Foundation receives Federal funds for the purpose of serving as a fiscal intermediary between Federal agencies, the Foundation may not receive such funds for the indirect costs of carrying out such purpose in an amount exceeding 10 percent of the direct costs of carrying out such purpose. The preceding sentence may not be construed as authorizing the expenditure of any grant under paragraph (1) for such purpose.

(j) COMMITTEE FOR ESTABLISHMENT OF FOUNDATION.—

(1) IN GENERAL.—There shall be established in accordance with this subsection a committee to carry out the functions described in paragraph (2) (which committee is referred to in this subsection as the “Committee”).

(2) FUNCTIONS.—The functions referred to in paragraph (1) for the Committee are as follows:

(A) To carry out such activities as may be necessary to incorporate the Foundation under the laws of the State involved, including serving as incorporators for the Foundation. Such activities shall include ensuring that the articles of incorporation for the Foundation require that the Foundation be established and operated in accordance with the applicable provisions of this part (or any successor to this part), including such provisions as may be in effect pursuant to amendments enacted after the date of the enactment of the Preventive Health Amendments of 1992¹.

(B) To ensure that the Foundation qualifies for and maintains the status described in subsection (e)(3) (regarding taxation).

(C) To establish the general policies and initial bylaws of the Foundation, which bylaws shall include the bylaws described in subsections (e)(3) and (f)(1).

(D) To provide for the initial operation of the Foundation, including providing for quarters, equipment, and staff.

(E) To appoint the initial members of the Board in accordance with the requirements established in subsection (f)(2)(A) for the composition of the Board, and in accordance with such other qualifications as the Committee may determine to be appropriate regarding such composition. Of the members so appointed—

(i) 2 shall be appointed to serve for a term of 3 years;

(ii) 2 shall be appointed to serve for a term of 4 years; and

(iii) 3 shall be appointed to serve for a term of 5 years.

¹Enacted October 27, 1992.

(3) COMPLETION OF FUNCTIONS OF COMMITTEE; INITIAL MEETING OF BOARD.—

(A) The Committee shall complete the functions required in paragraph (1) not later than September 30, 1994. The Committee shall terminate upon the expiration of the 30-day period beginning on the date on which the Secretary determines that the functions have been completed.

(B) The initial meeting of the Board shall be held not later than November 1, 1994.

(4) COMPOSITION.—The Committee shall be composed of 5 members, each of whom shall be a voting member. Of the members of the Committee—

(A) no fewer than 2 shall have broad, general experience in public health; and

(B) no fewer than 2 shall have broad, general experience in nonprofit private organizations (without regard to whether the individuals have experience in public health).

(5) CHAIR.—The Committee shall, from among the members of the Committee, designate an individual to serve as the chair of the Committee.

(6) TERMS; VACANCIES.—The term of members of the Committee shall be for the duration of the Committee. A vacancy in the membership of the Committee shall not affect the power of the Committee to carry out the duties of the Committee. If a member of the Committee does not serve the full term, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(7) COMPENSATION.—Members of the Committee may not receive compensation for service on the Committee. Members of the Committee may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Committee.

(8) COMMITTEE SUPPORT.—The Director of the Centers for Disease Control and Prevention may, from amounts available to the Director for the general administration of such Centers, provide staff and financial support to assist the Committee with carrying out the functions described in paragraph (2). In providing such staff and support, the Director may both detail employees and contract for assistance.

(9) GRANT FOR ESTABLISHMENT OF COMMITTEE.—

(A) With respect to a grant under paragraph (1)(A)(i) of subsection (i) for fiscal year 1993, an entity described in this paragraph is a private nonprofit entity with significant experience in domestic and international issues of public health. Not later than 180 days after the date of the enactment of the Preventive Health Amendments of 1992¹, the Secretary shall make the grant to such an entity (subject to the availability of funds under paragraph (2) of such subsection).

(B) The grant referred to in subparagraph (A) may be made to an entity only if the entity agrees that—

¹ Enacted October 27, 1992.

(i) the entity will establish a committee that is composed in accordance with paragraph (4); and

(ii) the entity will not select an individual for membership on the Committee unless the individual agrees that the Committee will operate in accordance with each of the provisions of this subsection that relate to the operation of the Committee.

(C) The Secretary may make a grant referred to in subparagraph (A) only if the applicant for the grant makes an agreement that the grant will not be expended for any purpose other than carrying out subparagraph (B). Such a grant may be made only if an application for the grant is submitted to the Secretary containing such agreement, and the application is in such form, is made in such manner, and contains such other agreements and such assurances and information as the Secretary determines to be necessary to carry out this paragraph.

TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL INSTITUTES OF HEALTH

ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH

SEC. 401. [281] (a) The National Institutes of Health is an agency of the Service.¹

(b)(1) The following national research institutes are agencies of the National Institutes of Health:

- (A) The National Cancer Institute.
 - (B) The National Heart, Lung, and Blood Institute.
 - (C) The National Institute of Diabetes and Digestive and Kidney Diseases.
 - (D) The National Institute of Arthritis and Musculoskeletal and Skin Diseases.
 - (E) The National Institute on Aging.
 - (F) The National Institute of Allergy and Infectious Diseases.
 - (G) The National Institute of Child Health and Human Development.
 - (H) The National Institute of Dental Research.
 - (I) The National Eye Institute.
 - (J) The National Institute of Neurological Disorders and Stroke.
 - (K) The National Institute of General Medical Sciences.
 - (L) The National Institute of Environmental Health Sciences.
 - (M) The National Institute on Deafness and Other Communication Disorders.
 - (N) The National Institute on Alcohol Abuse and Alcoholism.
 - (O) The National Institute on Drug Abuse.
 - (P) The National Institute of Mental Health.
 - (Q) The National Institute of Nursing Research.
- (2) The following entities are agencies of the National Institutes of Health:
- (A) The National Library of Medicine.
 - (B) The National Center for Research Resources.
 - (C) The John E. Fogarty International Center for Advanced Study in the Health Sciences.
 - (D) The National Center for Human Genome Research.
 - (E) The Office of Dietary Supplements.

(c)(1) The Secretary may establish in the National Institutes of Health one or more additional national research institutes to conduct and support research, training, health information, and other

¹ See footnote 1 on page 9.

programs with respect to any particular disease or groups of diseases or any other aspect of human health if—

(A) the Secretary determines that an additional institute is necessary to carry out such activities; and

(B) the additional institute is not established before the expiration of 180 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate written notice of the determination made under subparagraph (A) with respect to the institute.

(2) The Secretary may reorganize the functions of any national research institute and may abolish any national research institute if the Secretary determines that the institute is no longer required. A reorganization or abolition may not take effect under this paragraph before the expiration of 180 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate written notice of the reorganization or abolition.

(d) For purposes of this title, the term "national research institute" means a national research institute listed in subsection (b) or established under subsection (c). A reference to the National Institutes of Health includes its agencies.

APPOINTMENT AND AUTHORITY OF DIRECTOR OF NIH

SEC. 402. [282] (a) The National Institutes of Health shall be headed by the Director of the National Institutes of Health (hereafter in this title referred to as the "Director of NIH") who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

(b) In carrying out the purposes of section 301, the Secretary, acting through the Director of NIH—

(1) shall be responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

(2) shall coordinate and oversee the operation of the national research institutes and administrative entities within the National Institutes of Health;

(3) shall assure that research at or supported by the National Institutes of Health is subject to review in accordance with section 492;

(4) for the national research institutes and administrative entities within the National Institutes of Health—

(A) may acquire, construct, improve, repair, operate, and maintain, at the site of such institutes and entities, laboratories, and other research facilities, other facilities, equipment, and other real or personal property, and

(B) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of

buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

(5) may secure resources for research conducted by or through the National Institutes of Health;

(6) may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups and scientific program advisory committees as are needed to carry out the requirements of this title and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups;

(7) may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

(8) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(9) may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

(10) may accept voluntary and uncompensated services;

(11) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this title; and

(12) after consultation with the Director of the Office of Research on Women's Health, shall ensure that resources of the National Institutes of Health are sufficiently allocated for projects of research on women's health that are identified under section 486(b).

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (6). The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

(c) The Director of NIH may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(d)(1) The Director of NIH may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than 220 experts or consultants, with scientific or other professional qualifications, for the National Institutes of Health.

(2)(A) Except as provided in subparagraph (B), experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, United States

Code, for their travel to and from their place of service and for other expenses associated with their assignment.

(B) Expenses specified in subparagraph (A) shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(e) The Director of NIH shall—

(1) advise the agencies of the National Institutes of Health on medical applications of research;

(2) coordinate, review, and facilitate the systematic identification and evaluation of, clinically relevant information from research conducted by or through the national research institutes;

(3) promote the effective transfer of the information described in paragraph (2) to the health care community and to entities that require such information;

(4) monitor the effectiveness of the activities described in paragraph (3); and

(5) ensure that, after January 1, 1994, all new or revised health education and promotion materials developed or funded by the National Institutes of Health and intended for the general public are in a form that does not exceed a level of functional literacy, as defined in the National Literacy Act of 1991 (Public Law 102-73).

(f) There shall be in the National Institutes of Health an Associate Director for Prevention. The Director of NIH shall delegate to the Associate Director for Prevention the functions of the Director relating to the promotion of the disease prevention research programs of the national research institutes and the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities, including elementary, secondary, and post-secondary schools. The Associate Director shall—

(1) annually review the efficacy of existing policies and techniques used by the national research institutes to disseminate the results of disease prevention and behavioral research programs;

(2) recommend, coordinate, and oversee the modification or reconstruction of such policies and techniques to ensure maximum dissemination, using advanced technologies to the maximum extent practicable, of research results to such entities; and

(3) annually prepare and submit to the Director of NIH a report concerning the prevention and dissemination activities undertaken by the Associate Director, including—

(A) a summary of the Associate Director's review of existing dissemination policies and techniques together with a detailed statement concerning any modification or restructuring, or recommendations for modification or restructuring, of such policies and techniques; and

(B) a detailed statement of the expenditures made for the prevention and dissemination activities reported on and the personnel used in connection with such activities.

(g)(1)(A) In the case of entities described in subparagraph (B), the Director of NIH, acting through the Director of the National Center for Research Resources, shall establish a program to enhance the competitiveness of such entities in obtaining funds from the national research institutes for conducting biomedical and behavioral research.

(B) The entities referred to in subparagraph (A) are entities that conduct biomedical and behavioral research and are located in a State in which the aggregate success rate for applications to the national research institutes for assistance for such research by the entities in the State has historically constituted a low success rate of obtaining such funds, relative to such aggregate rate for such entities in other States.

(C) With respect to enhancing competitiveness for purposes of subparagraph (A), the Director of NIH, in carrying out the program established under such subparagraph, may—

(i) provide technical assistance to the entities involved, including technical assistance in the preparation of applications for obtaining funds from the national research institutes;

(ii) assist the entities in developing a plan for biomedical or behavioral research proposals; and

(iii) assist the entities in implementing such plan.

(2) The Director of NIH shall establish a program of supporting projects of biomedical or behavioral research whose principal researchers are individuals who have not previously served as the principal researchers of such projects supported by the Director.

(h) The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research.

(i)(1) There is established a fund, consisting of amounts appropriated under paragraph (3) and made available for the fund, for use by the Director of NIH to carry out the activities authorized in this Act for the National Institutes of Health. The purposes for which such fund may be expended include—

(A) providing for research on matters that have not received significant funding relative to other matters, responding to new issues and scientific emergencies, and acting on research opportunities of high priority;

(B) supporting research that is not exclusively within the authority of any single agency of such Institutes; and

(C) purchasing or renting equipment and quarters for activities of such Institutes.

(2) Not later than February 10 of each fiscal year, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities undertaken and expenditures made under this section during the preceding fiscal year. The report may contain such comments of the Secretary regarding this section as the Secretary determines to be appropriate.

(3) For the purpose of carrying out this subsection, there are authorized to be appropriated \$25,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

(j)(1) The Director of NIH may establish a program to provide day care services for the employees of the National Institutes of Health similar to those services provided by other Federal agencies (including the availability of day care service on a 24-hour-a-day basis).

(2) Any day care provider at the National Institutes of Health shall establish a sliding scale of fees that takes into consideration the income and needs of the employee.

(3) For purposes regarding the provision of day care services, the Director of NIH may enter into rental or lease purchase agreements.

(k) The Director of NIH shall carry out the program established in part F of title XII (relating to interagency research on trauma).

REPORT OF DIRECTOR OF NIH

SEC. 403. [283] The Secretary shall transmit to the President and to the Congress a biennial report which shall be prepared by the Director of NIH and which shall consist of—

(1) a description of the activities carried out by and through the National Institutes of Health and the policies respecting the programs of the National Institutes of Health and such recommendations respecting such policies as the Secretary considers appropriate;

(2) a description of the activities undertaken to improve grants and contracting accountability and technical and scientific peer review procedures of the National Institutes of Health and the national research institutes;

(3) the reports made by the Associate Director for Prevention under section 402(f) during the period for which the biennial report is prepared;

(4) a description of the health related behavioral research that has been supported by the National Institutes of Health in the preceding 2-year period, and a description of any plans for future activity in such area; and

(5) the biennial reports of the Directors of each of the national research institutes, the Director of the Division of Re-

search Resources,¹ and the Director of the National Center for Nursing Research.²

The first report under this section shall be submitted not later than July 1, 1986, and shall relate to the fiscal year ending September 30, 1985. The next report shall be submitted not later than December 30, 1988, and shall relate to the two-fiscal-year period ending on the preceding September 30. Each subsequent report shall be submitted not later than 90 days after the end of the two-fiscal-year period for which the report is to be submitted.

DES

SEC. 403A. [283a] (a) The Director of NIH shall establish a program for the conduct and support of research and training, the dissemination of health information, and other programs with respect to the diagnosis and treatment of conditions associated with exposure to the drug diethylstilbestrol (in this section referred to as 'DES').

(b) In carrying out subsection (a), the Director of NIH, after consultation with nonprofit private entities representing individuals who have been exposed to DES, shall conduct or support programs to educate health professionals and the public on the drug, including the importance of identifying and treating individuals who have been exposed to the drug.

(c) After consultation with the Office of Research on Women's Health, the Director of NIH, acting through the appropriate national research institutes, shall in carrying out subsection (a) conduct or support one or more longitudinal studies to determine the incidence of the following diseases or disorders in the indicated populations and the relationship of DES to the diseases or disorders:

(1) In the case of women to whom (on or after January 1, 1938) DES was administered while the women were pregnant, the incidence of all diseases and disorders (including breast cancer, gynecological cancers, and impairments of the immune system, including autoimmune disease).

(2) In the case of women exposed to DES in utero, the incidence of clear cell cancer (including recurrences), the long-term health effects of such cancer, and the effects of treatments for such cancer.

(3) In the case of men and women exposed to DES in utero, the incidence of all diseases and disorders (including impairments of the reproductive and autoimmune systems).

(4) In the case of children of men or women exposed to DES in utero, the incidence of all diseases and disorders.

(d) For purposes of this section, an individual shall be considered to have been exposed to DES in utero if, during the pregnancy that resulted in the birth of such individual, DES was (on or after January 1, 1938) administered to the biological mother of the individual.

¹Now the National Center for Research Resources. See section 1501 of Public Law 103-43 (107 Stat. 172).

²Now the National Institute of Nursing Research. See section 1511 of Public Law 103-43 (107 Stat. 178).

(e) In addition to any other authorization of appropriations available for the purpose of carrying out this section, there are authorized to be appropriated for such purpose such sums as may be necessary for each of the fiscal years 1993 through 1996.

OFFICE OF RESEARCH ON MINORITY HEALTH

SEC. 404. [283b] (a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Research on Minority Health (in this section referred to as the “Office”). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

(b) PURPOSE.—The Director of the Office shall—

(1) identify projects of research on minority health that should be conducted or supported by the national research institutes;

(2) identify multidisciplinary research relating to research on minority health that should be so conducted or supported;

(3) promote coordination and collaboration among entities conducting research identified under paragraph (1) or (2);

(4) encourage the conduct of such research by entities receiving funds from the national research institutes;

(5) recommend an agenda for conducting and supporting such research;

(6) promote the sufficient allocation of the resources of the national research institutes for conducting and supporting such research; and

(7) assist in the administration of section 492B with respect to the inclusion of members of minority groups as subjects in clinical research.

OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH

SEC. 404A. [283c] (a) There is established within the Office of the Director of NIH an office to be known as the Office of Behavioral and Social Sciences Research (in this section referred to as the “Office”). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

(b)(1) With respect to research on the relationship between human behavior and the development, treatment, and prevention of medical conditions, the Director of the Office shall—

(A) coordinate research conducted or supported by the agencies of the National Institutes of Health; and

(B) identify projects of behavioral and social sciences research that should be conducted or supported by the national research institutes, and develop such projects in cooperation with such institutes.

(2) Research authorized under paragraph (1) includes research on teen pregnancy, infant mortality, violent behavior, suicide, and homelessness. Such research does not include neurobiological research, or research in which the behavior of an organism is observed for the purpose of determining activity at the cellular or molecular level.

CHILDREN'S VACCINE INITIATIVE

SEC. 404B. [283d] (a) DEVELOPMENT OF NEW VACCINES.—The Secretary, in consultation with the Director of the National Vaccine Program under title XXI and acting through the Directors of the National Institute for Allergy and Infectious Diseases, the National Institute for Child Health and Human Development, the National Institute for Aging, and other public and private programs, shall carry out activities, which shall be consistent with the global Children's Vaccine Initiative, to develop affordable new and improved vaccines to be used in the United States and in the developing world that will increase the efficacy and efficiency of the prevention of infectious diseases. In carrying out such activities, the Secretary shall, to the extent practicable, develop and make available vaccines that require fewer contacts to deliver, that can be given early in life, that provide long lasting protection, that obviate refrigeration, needles and syringes, and that protect against a larger number of diseases.

(b) REPORT.—In the report required in section 2104, the Secretary, acting through the Director of the National Vaccine Program under title XXI, shall include information with respect to activities and the progress made in implementing the provisions of this section and achieving its goals.

(c) AUTHORIZATION OF APPROPRIATIONS.—In addition to any other amounts authorized to be appropriated for activities of the type described in this section, there are authorized to be appropriated to carry out this section \$20,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

PLAN FOR USE OF ANIMALS IN RESEARCH

SEC. 404C. [283e] (a) The Director of NIH, after consultation with the committee established under subsection (e), shall prepare a plan—

(1) for the National Institutes of Health to conduct or support research into—

(A) methods of biomedical research and experimentation that do not require the use of animals;

(B) methods of such research and experimentation that reduce the number of animals used in such research;

(C) methods of such research and experimentation that produce less pain and distress in such animals; and

(D) methods of such research and experimentation that involve the use of marine life (other than marine mammals);

(2) for establishing the validity and reliability of the methods described in paragraph (1);

(3) for encouraging the acceptance by the scientific community of such methods that have been found to be valid and reliable; and

(4) for training scientists in the use of such methods that have been found to be valid and reliable.

(b) Not later than October 1, 1993, the Director of NIH shall submit to the Committee on Energy and Commerce of the House

of Representatives, and to the Committee on Labor and Human Resources of the Senate, the plan required in subsection (a) and shall begin implementation of the plan.

(c) The Director of NIH shall periodically review, and as appropriate, make revisions in the plan required under subsection (a). A description of any revision made in the plan shall be included in the first biennial report under section 403 that is submitted after the revision is made.

(d) The Director of NIH shall take such actions as may be appropriate to convey to scientists and others who use animals in biomedical or behavioral research or experimentation information respecting the methods found to be valid and reliable under subsection (a)(2).

(e)(1) The Director of NIH shall establish within the National Institutes of Health a committee to be known as the Interagency Coordinating Committee on the Use of Animals in Research (in this subsection referred to as the "Committee").

(2) The Committee shall provide advice to the Director of NIH on the preparation of the plan required in subsection (a).

(3) The Committee shall be composed of—

(A) the Directors of each of the national research institutes and the Director of the Center for Research Resources (or the designees of such Directors); and

(B) representatives of the Environmental Protection Agency, the Food and Drug Administration, the Consumer Product Safety Commission, the National Science Foundation, and such additional agencies as the Director of NIH determines to be appropriate, which representatives shall include not less than one veterinarian with expertise in laboratory-animal medicine.

REQUIREMENTS REGARDING SURVEYS OF SEXUAL BEHAVIOR

SEC. 404D. [283f] With respect to any survey of human sexual behavior proposed to be conducted or supported through the National Institutes of Health, the survey may not be carried out unless—

(1) the proposal has undergone review in accordance with any applicable requirements of sections 491 and 492; and

(2) the Secretary, in accordance with section 492A, makes a determination that the information expected to be obtained through the survey will assist—

(A) in reducing the incidence of sexually transmitted diseases, the incidence of infection with the human immunodeficiency virus, or the incidence of any other infectious disease; or

(B) in improving reproductive health or other conditions of health.

OFFICE OF ALTERNATIVE MEDICINE

SEC. 404E. [283g] (a) There is established within the Office of the Director of NIH an office to be known as the Office of Alternative Medicine (in this section referred to as the "Office"), which shall be headed by a director appointed by the Director of NIH.

(b) The purpose of the Office is to facilitate the evaluation of alternative medical treatment modalities, including acupuncture and Oriental medicine, homeopathic medicine, and physical manipulation therapies.

(c) The Secretary shall establish an advisory council for the purpose of providing advice to the Director of the Office on carrying out this section. Section 222 applies to such council to the same extent and in the same manner as such section applies to committees or councils established under such section.

(d) In carrying out subsection (b), the Director of the Office shall—

(1) establish an information clearinghouse to exchange information with the public about alternative medicine;

(2) support research training—

(A) for which fellowship support is not provided under section 487; and

(B) that is not residency training of physicians or other health professionals; and

(3)(A) prepare biennial reports on the activities carried out or to be carried out by the Office; and

(B) submit each such report to the Director of NIH for inclusion in the biennial report under section 403.

PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

APPOINTMENT AND AUTHORITY OF THE DIRECTORS OF THE NATIONAL RESEARCH INSTITUTES

SEC. 405. [284] (a) The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes shall be appointed by the Secretary. Each Director of a national research institute shall report directly to the Director of NIH.

(b)(1) In carrying out the purposes of section 301 with respect to human diseases or disorders or other aspects of human health for which the national research institutes were established, the Secretary, acting through the Director of each national research institute—

(A) shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to—

(i) the maintenance of health,

(ii) the detection, diagnosis, treatment, and prevention of human diseases and disorders,

(iii) the rehabilitation of individuals with human diseases, disorders, and disabilities, and

(iv) the expansion of knowledge of the processes underlying human diseases, disorders, and disabilities, the processes underlying the normal and pathological functioning of the body and its organ systems, and the processes underlying the interactions between the human organism and the environment;

(B) may, subject to the peer review prescribed under section 492(b) and any advisory council review under section

406(a)(3)(A)(i), conduct the research, investigations, experiments, demonstrations, and studies referred to in subparagraph (A);

(C) may conduct and support research training (i) for which fellowship support is not provided under section 487, and (ii) which is not residency training of physicians or other health professionals;

(D) may develop, implement, and support demonstrations and programs for the application of the results of the activities of the institute to clinical practice and disease prevention activities;

(E) may develop, conduct, and support public and professional education and information programs;

(F) may secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research;

(G) may make available the facilities of the institute to appropriate entities and individuals engaged in research activities and cooperate with and assist Federal and State agencies charged with protecting the public health;

(H) may accept unconditional gifts made to the institute for its activities, and, in the case of gifts of a value in excess of \$50,000, establish suitable memorials to the donor;

(I) may secure for the institute consultation services and advice of persons from the United States or abroad;

(J) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(K) may accept voluntary and uncompensated services; and

(L) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute.

The indemnification provisions of section 2354, title 10, United States Code, shall apply with respect to contracts entered into under this subsection and section 402(b).

(2) Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements. The Secretary, acting through the Director of each national research institute—

(A) may enter into a contract for research, training, or demonstrations only if the contract has been recommended after technical and scientific peer review required by regulations under section 492;

(B) may make grants and cooperative agreements under paragraph (1) for research, training, or demonstrations, except that—

(i) if the direct cost of the grant or cooperative agreement to be made does not exceed \$50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 492, and

(ii) if the direct cost of the grant or cooperative agreement to be made exceeds \$50,000, such grant or coopera-

tive agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 492 and is recommended under section 406(a)(3)(A)(ii) by the advisory council for the national research institute involved; and

(C) shall, subject to section 2353(d)(2), receive from the President and the Office of Management and Budget directly all funds appropriated by the Congress for obligation and expenditure by the Institute.

(c) In carrying out subsection (b), each Director of a national research institute—

(1) shall coordinate, as appropriate, the activities of the institute with similar programs of other public and private entities;

(2) shall cooperate with the Directors of the other national research institutes in the development and support of multidisciplinary research and research that involves more than one institute;

(3) may, in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

(A) establish technical and scientific peer review groups in addition to those appointed under section 402(b)(6); and

(B) appoint the members of peer review groups established under subparagraph (A); and

(4) may publish, or arrange for the publication of, information with respect to the purpose of the Institute without regard to section 501 of title 44, United States Code.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (3).

ADVISORY COUNCILS

SEC. 406. [284a] (a)(1) Except as provided in subsection (h), the Secretary shall appoint an advisory council for each national research institute which (A) shall advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute on matters related to the activities carried out by and through the institute and the policies respecting such activities, and (B) shall carry out the special functions prescribed by part C.

(2) Each advisory council for a national research institute may recommend to the Secretary acceptance, in accordance with section 231, of conditional gifts for study, investigation, or research respecting the diseases, disorders, or other aspect of human health with respect to which the institute was established, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the institute.

(3) Each advisory council for a national research institute—

(A)(i) may on the basis of the materials provided under section 492(b)(2) respecting research conducted at the institute, make recommendations to the Director of the institute respecting such research,

(ii) may review applications for grants and cooperative agreements for research or training and for which advisory

council approval is required under section 405(b)(2) and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspect of human health with respect to which the institute was established and with the approval of the Director of the institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b)(1) Each advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary. The ex officio members shall be nonvoting members.

(2) The ex officio members of an advisory council shall consist of—

(A) the Secretary, the Director of NIH, the Director of the national research institute for which the council is established, the Chief Medical Director of the Department of Veterans Affairs or the Chief Dental Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of an advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including not less than two individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the national research institute for which the advisory council is established.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of an advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule.

(c) The term of office of an appointed member of an advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remain-

der of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term for 180 days after the date of such expiration. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) The chairman of an advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the national research institute for which the advisory council is established to be the chairman of the advisory council. The term of office of the chairman shall be two years.

(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the national research institute for which it was established, but at least three times each fiscal year. The location of the meetings of each advisory council is subject to the approval of the Director of the national research institute for which the advisory council was established.

(f) The Director of the national research institute for which an advisory council is established shall designate a member of the staff of the institute to serve as the executive secretary of the advisory council. The Director of such institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of such institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

(g) Each advisory council may prepare, for inclusion in the biennial report made under section 407, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the national research institute for which it was established in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the institute. Each advisory council may prepare such additional reports as it may determine appropriate.

(h)(1) Except as provided in paragraph (2), this section does not terminate the membership of any advisory council for a national research institute which was in existence on the date of enactment of the Health Research Extension Act of 1985. After such date—

(A) the Secretary shall make appointments to each such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

(B) each advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

(C) the Director of each national research institute shall perform for such advisory council the functions prescribed by this section.

(2)(A) The National Cancer Advisory Board shall be the advisory council for the National Cancer Institute. This section applies to the National Cancer Advisory Board, except that—

(i) appointments to such Board shall be made by the President;

(ii) the term of office of an appointed member shall be 6 years;

(iii) of the members appointed to the Board not less than five members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors);

(iv) the chairman of the Board shall be selected by the President from the appointed members and shall serve as chairman for a term of two years;

(v) the ex officio members of the Board shall be nonvoting members and shall be the Secretary, the Director of the Office of Science and Technology Policy, the Director of NIH, the Chief Medical Director of the Department of Veterans Affairs, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Energy Research of the Department of Energy (or the designees of such officers); and

(vi) the Board shall meet at least four times each fiscal year.

(B) This section applies to the advisory council to the National Heart, Lung, and Blood Institute, except that the advisory council shall meet at least four times each fiscal year.

BIENNIAL REPORT

SEC. 407. [284b] The Director of each national research institute, after consultation with the advisory council for the institute, shall prepare for inclusion in the biennial report made under section 403 a biennial report which shall consist of a description of the activities of the institute and program policies of the Director of the institute in the fiscal years respecting which the report is prepared. The Director of each national research institute may prepare such additional reports as the Director determines appropriate. The Director of each national research institute shall provide the advisory council for the institute an opportunity for the submission of the written comments referred to in section 406(g).

CERTAIN USES OF FUNDS

SEC. 408. [284c] (a)(1) Except as provided in paragraph (2), the sum of the amounts obligated in any fiscal year for administrative expenses of the National Institutes of Health may not exceed

an amount which is 5.5 percent of the total amount appropriated for such fiscal year for the National Institutes of Health.

(2) Paragraph (1) does not apply to the National Library of Medicine, the National Center for Nursing Research,¹ the John E. Fogarty International Center for Advanced Study in the Health Sciences, the Warren G. Magnuson Clinical Center, and the Office of Medical Applications of Research.

(3) For purposes of paragraph (1), the term "administrative expenses" means expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health. In identifying expenses incurred for such support and administration the Secretary shall consult with the Comptroller General of the United States.

(4) Not later than December 31, 1987, and December 31 of each succeeding year, the Secretary shall report to the Congress the amount obligated in the fiscal year preceding such date for administrative expenses of the National Institutes of Health and the total amount appropriated for the National Institutes of Health for such fiscal year. The Secretary shall consult with the Comptroller General of the United States in preparing each report.

(b) For fiscal year 1989 and subsequent fiscal years, amounts made available to the National Institutes of Health shall be available for payment of nurses and allied health professionals in accordance with payment authorities, scheduling options, benefits, and other authorities provided under chapter 73 of title 38, United States Code, for nurses of the Department of Veterans Affairs.

DEFINITIONS

SEC. 409. [284d] For purposes of this title, the term "health services research" means research endeavors that study the impact of the organization, financing and management of health services on the quality, cost, access to and outcomes of care. Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions.

RESEARCH ON OSTEOPOROSIS, PAGET'S DISEASE, AND RELATED BONE DISORDERS

SEC. 409A. [284e] (a) ESTABLISHMENT.—The Directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute on Aging, the National Institute of Dental Research, and the National Institute of Diabetes and Digestive and Kidney Diseases, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning osteoporosis, Paget's disease, and related bone disorders.

(b) COORDINATION.—The Directors referred to in subsection (a) shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and the Interagency Task Force on Aging Research.

¹ See footnote 2 on page 270.

(c) INFORMATION CLEARINGHOUSE.—

(1) IN GENERAL.—In order to assist in carrying out the purpose described in subsection (a), the Director of NIH shall provide for the establishment of an information clearinghouse on osteoporosis and related bone disorders to facilitate and enhance knowledge and understanding on the part of health professionals, patients, and the public through the effective dissemination of information.

(2) ESTABLISHMENT THROUGH GRANT OR CONTRACT.—For the purpose of carrying out paragraph (1), the Director of NIH shall enter into a grant, cooperative agreement, or contract with a nonprofit private entity involved in activities regarding the prevention and control of osteoporosis and related bone disorders.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$40,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH
INSTITUTES

Subpart 1—National Cancer Institute

PURPOSE OF INSTITUTE

SEC. 410. [285] The general purpose of the National Cancer Institute (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

NATIONAL CANCER PROGRAM

SEC. 411. [285a] The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute.

CANCER CONTROL PROGRAMS

SEC. 412. [285a-1] The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include—

(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting—

(A) the detection, diagnosis, prevention, and treatment of cancer,

(B) the continuing care of cancer patients and the families of cancer patients, and

(C) rehabilitation and counseling respecting cancer, to physicians and other health professionals who provide care to individuals who have cancer;

(2) the demonstration of and the education of students of the health professions and health professionals in—

(A) effective methods for the prevention and early detection of cancer and the identification of individuals with a high risk of developing cancer, and

(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

(3) the demonstration of new methods for the dissemination of information to the general public concerning the prevention, early detection, diagnosis, and treatment and control of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

SPECIAL AUTHORITIES OF THE DIRECTOR

SEC. 413. [285a-2] (a)(1) The Director of the Institute shall establish an information and education program to collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to cancer patients and their families, physicians and other health professionals, and the general public, information on cancer research, diagnosis, prevention, and treatment (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer). The Director of the Institute may take such action as may be necessary to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the public and between the Institute and other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

(2) In carrying out paragraph (1), the Director of the Institute shall—

(A) provide public and patient information and education programs, providing information that will help individuals take personal steps to reduce their risk of cancer, to make them aware of early detection techniques and to motivate appropriate utilization of those techniques, to help individuals deal with cancer if it strikes, and to provide information to improve long-term survival;

(B) continue and expand programs to provide physicians and the public with state-of-the-art information on the treatment of particular forms of cancers, and to identify those clinical trials that might benefit patients while advancing knowledge of cancer treatment;

(C) assess the incorporation of state-of-the-art cancer treatments into clinical practice and the extent to which cancer patients receive such treatments and include the results of such assessments in the biennial reports required under section 407;

(D) maintain and operate the International Cancer Research Data Bank, which shall collect, catalog, store, and disseminate insofar as feasible the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country; and

(E) to the extent practicable, in disseminating the results of such cancer research and treatment, utilize information systems available to the public.

(b) The Director of the Institute in carrying out the National Cancer Program—

(1) shall establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for cancer research and set standards of safety and care for persons using such materials;

(2) shall, in consultation with the advisory council for the Institute, support (A) research in the cancer field outside the United States by highly qualified foreign nationals which can be expected to benefit the American people, (B) collaborative research involving American and foreign participants, and (C) the training of American scientists abroad and foreign scientists in the United States;

(3) shall, in consultation with the advisory council for the Institute, support appropriate programs of education and training (including continuing education and laboratory and clinical research training);

(4) shall encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

(5) may obtain (after consultation with the advisory council for the Institute and in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

(6)(A) may, in consultation with the advisory council for the Institute, acquire, construct, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(7) may, in consultation with the advisory council for the Institute, appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments to advise the Director with respect to the Director's functions;

(8) may, subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), enter into such contracts, leases, cooperative agreements, as may be necessary in the conduct of functions of the Director, with any public agency, or with any person, firm, association, corporation, or educational institution; and

(9) shall, notwithstanding section 405(a), prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Institute's advisory council.

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (5) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (5) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

SEC. 414. [285a-3] (a)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, control, and treatment methods for cancer.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(b) Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) construction (notwithstanding any limitation under section 496);

(2) staffing and other basic operating costs, including such patient care costs as are required for research;

(3) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer; and

(4) demonstration purposes.

As used in this paragraph, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which National Research Service Awards may be provided under section 487.

(c) Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

PRESIDENT'S CANCER PANEL

SEC. 415. [285a-4] (a)(1) The President's Cancer Panel (hereafter in this section referred to as the "Panel") shall be composed of three persons appointed by the President who by virtue of their training, experience, and background are exceptionally qualified to appraise the National Cancer Program. At least two members of the Panel shall be distinguished scientists or physicians.

(2)(A) Members of the Panel shall be appointed for three-year terms, except that (i) any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of such term, and (ii) a member may serve until the member's successor has taken office. If a vacancy occurs in the Panel, the President shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

(B) The President shall designate one of the members to serve as the chairman of the Panel for a term of one year.

(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties as members of the Panel and shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment.

(3) The Panel shall meet at the call of the chairman, but not less often than four times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and the chairman shall make such transcript available to the public.

(b) The Panel shall monitor the development and execution of the activities of the National Cancer Program, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the National Cancer Program and shall submit to the President, the Secretary, and the Congress an annual evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct.

ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 416. [285a-5] (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of cancer. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

BREAST AND GYNECOLOGICAL CANCERS

SEC. 417. [285a-6] (a) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on breast cancer, ovarian cancer, and other cancers of the reproductive system of women.

(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to breast cancer and other cancers of the reproductive system of women.

(c) PROGRAMS FOR BREAST CANCER.—

(1) IN GENERAL.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, breast cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

(A) basic research concerning the etiology and causes of breast cancer;

(B) clinical research and related activities concerning the causes, prevention, detection and treatment of breast cancer;

(C) control programs with respect to breast cancer in accordance with section 412, including community-based programs designed to assist women who are members of medically underserved populations, low-income populations, or minority groups;

(D) information and education programs with respect to breast cancer in accordance with section 413; and

(E) research and demonstration centers with respect to breast cancer in accordance with section 414, including the development and operation of centers for breast cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and treatment research and related activities on breast cancer.

Not less than six centers shall be operated under subparagraph (E). Activities of such centers should include supporting

new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

(2) IMPLEMENTATION OF PLAN FOR PROGRAMS.—

(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 413(9). The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

(B) Not later than October 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary and the Director of NIH.

(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

(d) OTHER CANCERS.—In carrying out subsection (a), the Director of the Institute shall conduct or support research on ovarian cancer and other cancers of the reproductive system of women. Activities under such subsection shall provide for the conduct and support of—

(1) basic research concerning the etiology and causes of ovarian cancer and other cancers of the reproductive system of women;

(2) clinical research and related activities into the causes, prevention, detection and treatment of ovarian cancer and other cancers of the reproductive system of women;

(3) control programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 412;

(4) information and education programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 413; and

(5) research and demonstration centers with respect to ovarian cancer and cancers of the reproductive system in accordance with section 414.

(e) REPORT.—The Director of the Institute shall prepare, for inclusion in the biennial report submitted under section 407, a report that describes the activities of the National Cancer Institute under the research programs referred to in subsection (a), that shall include—

(1) a description of the research plan with respect to breast cancer prepared under subsection (c);

(2) an assessment of the development, revision, and implementation of such plan;

(3) a description and evaluation of the progress made, during the period for which such report is prepared, in the research programs on breast cancer and cancers of the reproductive system of women;

(4) a summary and analysis of expenditures made, during the period for which such report is made, for activities with respect to breast cancer and cancers of the reproductive system of women conducted and supported by the National Institutes of Health; and

(5) such comments and recommendations as the Director considers appropriate.

PROSTATE CANCER

SEC. 417A. [286a-7] (a) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on prostate cancer.

(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to prostate cancer.

(c) PROGRAMS.—

(1) IN GENERAL.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, prostate cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

(A) basic research concerning the etiology and causes of prostate cancer;

(B) clinical research and related activities concerning the causes, prevention, detection and treatment of prostate cancer;

(C) prevention and control and early detection programs with respect to prostate cancer in accordance with section 412, particularly as it relates to intensifying research on the role of prostate specific antigen for the screening and early detection of prostate cancer;

(D) an Inter-Institute Task Force, under the direction of the Director of the Institute, to provide coordination between relevant National Institutes of Health components of research efforts on prostate cancer;

(E) control programs with respect to prostate cancer in accordance with section 412;

(F) information and education programs with respect to prostate cancer in accordance with section 413; and

(G) research and demonstration centers with respect to prostate cancer in accordance with section 414, including the development and operation of centers for prostate

cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and control, treatment, research, and related activities on prostate cancer.

Not less than six centers shall be operated under subparagraph (G). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

(2) IMPLEMENTATION OF PLAN FOR PROGRAMS.—

(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 413(9). The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

(B) Not later than October 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

AUTHORIZATION OF APPROPRIATIONS

SEC. 417B. [286a-8] (a) ACTIVITIES GENERALLY.—For the purpose of carrying out this subpart, there are authorized to be appropriated \$2,728,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

(b) BREAST CANCER AND GYNECOLOGICAL CANCERS.—

(1) BREAST CANCER.—

(A) For the purpose of carrying out subparagraph (A) of section 417(c)(1), there are authorized to be appropriated \$225,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

(B) For the purpose of carrying out subparagraphs (B) through (E) of section 417(c)(1), there are authorized to be appropriated \$100,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in ad-

dition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

(2) OTHER CANCERS.—For the purpose of carrying out subsection (d) of section 417, there are authorized to be appropriated \$75,000,000 for fiscal year 1994, and such sums as are necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

(c) PROSTATE CANCER.—For the purpose of carrying out section 417A, there are authorized to be appropriated \$72,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

(d) ALLOCATION REGARDING CANCER CONTROL.—

(1) IN GENERAL.—Of the amounts appropriated for the National Cancer Institute for a fiscal year, the Director of the Institute shall make available not less than the applicable percentage specified in paragraph (2) for carrying out the cancer control activities authorized in section 412 and for which budget estimates are made under section 413(b)(9) for the fiscal year.

(2) APPLICABLE PERCENTAGE.—The percentage referred to in paragraph (1) is—

(A) 7 percent, in the case of fiscal year 1994;

(B) 9 percent, in the case of fiscal year 1995; and

(C) 10 percent, in the case of fiscal year 1996 and each subsequent fiscal year.

Subpart 2—National Heart, Lung, and Blood Institute

PURPOSE OF THE INSTITUTE

SEC. 418. [285b] The general purpose of the National Heart, Lung, and Blood Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood products and the management of blood resources.

HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PREVENTION AND CONTROL PROGRAMS

SEC. 419. [285b–1] (a) The Director of the Institute shall conduct and support programs for the prevention and control of heart, blood vessel, lung, and blood diseases. Such programs shall include community-based and population-based programs carried out in cooperation with other Federal agencies, with public health agencies of State or local governments, with nonprofit private entities that are community-based health agencies, or with other appropriate public or nonprofit private entities.

(b) In carrying out programs under subsection (a), the Director of the Institute shall give special consideration to the prevention and control of heart, blood vessel, lung, and blood diseases in chil-

dren, and in populations that are at increased risk with respect to such diseases.

INFORMATION AND EDUCATION

SEC. 420. [285b-2] The Director of the Institute shall collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to patients, families of patients, physicians and other health professionals, and the general public, information on research, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases, the maintenance of health to reduce the incidence of such diseases, and on the use of blood and blood products and the management of blood resources. In carrying out this section, the Director of the Institute shall place special emphasis upon the utilization of collaborative efforts with both the public and private sectors to—

(1) increase the awareness and knowledge of health care professionals and the public regarding the prevention of heart and blood vessel, lung, and blood diseases and the utilization of blood resources; and

(2) develop and disseminate to health professionals, patients and patient families, and the public information designed to encourage adults and children to adopt healthful practices concerning the prevention of such diseases.

NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES PROGRAM

SEC. 421. [285b-3] (a)(1) The National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this subpart referred to as the "Program" may provide for—

(A) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;

(B) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

(C) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including the provision of emergency medical services), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

(D) establishment of programs that will focus and apply scientific and technological efforts involving the biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on the refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of and rehabilitation from such diseases;

(E) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;

(F) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of blood resources in the United States, including the collection, preservation, fractionation, and distribution of blood and blood products;

(G) the education (including continuing education) and training of scientists, clinical investigators, and educators, in fields and specialties (including computer sciences) requisite to the conduct of clinical programs respecting heart, blood vessel, lung, and blood diseases and blood resources;

(H) public and professional education relating to all aspects of such diseases, including the prevention of such diseases, and the use of blood and blood products and the management of blood resources;

(I) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, hemolytic diseases such as sickle cell anemia and Cooley's anemia, and hemophilic diseases) and for the development and demonstration of diagnostic, treatment, and preventive approaches to such diseases; and

(J) establishment of programs for study, research, development, demonstrations and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, or blood diseases.

(2) The Program shall be coordinated with other national research institutes to the extent that they have responsibilities respecting such diseases and shall give special emphasis to the continued development in the Institute of programs related to the causes of stroke and to effective coordination of such programs with related stroke programs in the National Institute of Neurological and Communicative Disorders and Stroke. The Director of the Institute, with the advice of the advisory council for the Institute, shall revise annually the plan for the Program and shall carry out the Program in accordance with such plan.

(b) In carrying out the Program, the Director of the Institute, under policies established by the Director of NIH—

(1) may, after consultation with the advisory council for the Institute, obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of such service) the services of not more than one hundred experts or consultants who have scientific or professional qualifications;

(2)(A) may, in consultation with the advisory council for the Institute, acquire and construct, improve, repair, operate, alter, renovate, and maintain, heart, blood vessel, lung, and blood disease and blood resource laboratories, research, training, and other facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(3) subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), may enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary in the conduct of the Director's functions, with any public agency, or with any person, firm, association, corporation, or educational institutions;

(4) may make grants to public and nonprofit private entities to assist in meeting the cost of the care of patients in hospitals, clinics, and related facilities who are participating in research projects; and

(5) shall, in consultation with the advisory council for the Institute, conduct appropriate intramural training and education programs, including continuing education and laboratory and clinical research training programs.

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES, SICKLE CELL ANEMIA, AND BLOOD RESOURCES

SEC. 422. [285b-4] (a)(1) The Director of the Institute may provide, in accordance with subsection (c), for the development of—

(A) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment and rehabilitation methods (including methods of providing emergency medical services) for heart and blood vessel diseases;

(B) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and

treatment and rehabilitation methods (including methods of providing emergency medical services) for lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children);

(C) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood diseases and research into blood, in the use of blood products and in the management of blood resources; and

(D) three centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment (including genetic studies, intrauterine environment studies, postnatal studies, heart arrhythmias, and acquired heart disease and preventive cardiology) for cardiovascular diseases in children.

(2) The centers developed under paragraph (1) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, pulmonary, and blood diseases:

(A) Programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular, pulmonary, and blood diseases.

(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such diseases.

(C) Programs to develop health professions and allied health professions personnel highly skilled in the prevention of such diseases.

(D) Programs to develop improved methods of providing emergency medical services for persons with such diseases.

(E) Programs of continuing education for health and allied health professionals in the diagnosis, prevention, and treatment of such diseases and the maintenance of health to reduce the incidence of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases and the maintenance of health.

(3) The research, training, and demonstration activities carried out through any such center may relate to any one or more of the diseases referred to in paragraph (1) of this subsection.

(b) The Director of the Institute shall provide, in accordance with subsection (c), for the development of ten centers for basic and clinical research into the diagnosis, treatment, and control of sickle cell anemia.

(c)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Di-

rector of NIH and after consultation with the Institute's advisory council.

(3) Federal payments made under a cooperative agreement or grant under paragraph (1) may be used for—

(A) construction (notwithstanding any limitation under section 496);

(B) staffing and other basic operating costs, including such patient care costs as are required for research;

(C) training, including training for allied health professionals; and

(D) demonstration purposes.

As used in this subsection, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which National Research Service Awards may be provided under section 487.

(4) Support of a center under paragraph (1) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 423. [285b-6] (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of heart, blood vessel, lung, and blood diseases. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

NATIONAL CENTER ON SLEEP DISORDERS RESEARCH

SEC. 424. [285b-7] (a) Not later than 1 year after the date of the enactment of the National Institutes of Health Revitalization Act of 1993, the Director of the Institute shall establish the National Center on Sleep Disorders Research (in this section referred to as the "Center"). The Center shall be headed by a director, who shall be appointed by the Director of the Institute.

(b) The general purpose of the Center is—

(1) the conduct and support of research, training, health information dissemination, and other activities with respect to sleep disorders, including biological and circadian rhythm research, basic understanding of sleep, chronobiological and other sleep related research; and

(2) to coordinate the activities of the Center with similar activities of other Federal agencies, including the other agencies of the National Institutes of Health, and similar activities of other public entities and nonprofit entities.

(c)(1) The Director of the National Institutes of Health shall establish a board to be known as the Sleep Disorders Research Advisory Board (in this section referred to as the "Advisory Board").

(2) The Advisory Board shall advise, assist, consult with, and make recommendations to the Director of the National Institutes of Health, through the Director of the Institute, and the Director of the Center concerning matters relating to the scientific activities carried out by and through the Center and the policies respecting such activities, including recommendations with respect to the plan required in subsection (c).

(3)(A) The Director of the National Institutes of Health shall appoint to the Advisory Board 12 appropriately qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, eight shall be representatives of health and scientific disciplines with respect to sleep disorders and four shall be individuals representing the interests of individuals with or undergoing treatment for sleep disorders.

(B) The following officials shall serve as ex officio members of the Advisory Board:

(i) The Director of the National Institutes of Health.

(ii) The Director of the Center.

(iii) The Director of the National Heart, Lung and Blood Institute.

(iv) The Director of the National Institute of Mental Health.

(v) The Director of the National Institute on Aging.

(vi) The Director of the National Institute of Child Health and Human Development.

(vii) The Director of the National Institute of Neurological Disorders and Stroke.

(viii) The Assistant Secretary for Health.

(ix) The Assistant Secretary of Defense (Health Affairs).

(x) The Chief Medical Director of the Veterans' Administration.

(4) The members of the Advisory Board shall, from among the members of the Advisory Board, designate an individual to serve as the chair of the Advisory Board.

(5) Except as inconsistent with, or inapplicable to, this section, the provisions of section 406 shall apply to the advisory board established under this section in the same manner as such provisions apply to any advisory council established under such section.

(d)(1) After consultation with the Director of the Center and the advisory board established under subsection (c), the Director of the National Institutes of Health shall develop a comprehensive plan for the conduct and support of sleep disorders research.

(2) The plan developed under paragraph (1) shall identify priorities with respect to such research and shall provide for the coordination of such research conducted or supported by the agencies of the National Institutes of Health.

(3) The Director of the National Institutes of Health (after consultation with the Director of the Center and the advisory board established under subsection (c)) shall revise the plan developed under paragraph (1) as appropriate.

(e) The Director of the Center, in cooperation with the Centers for Disease Control and Prevention, is authorized to coordinate activities with the Department of Transportation, the Department of Defense, the Department of Education, the Department of Labor, and the Department of Commerce to collect data, conduct studies, and disseminate public information concerning the impact of sleep disorders and sleep deprivation.

AUTHORIZATION OF APPROPRIATIONS

SEC. 425. [285b-8] For the purpose of carrying out this subpart, there are authorized to be appropriated \$1,500,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

Subpart 3—National Institute of Diabetes and Digestive and Kidney Diseases

PURPOSE OF THE INSTITUTE

SEC. 426. [285c] The general purpose of the National Institute of Diabetes and Digestive and Kidney Diseases (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases.

DATA SYSTEMS AND INFORMATION CLEARINGHOUSES

SEC. 427. [285c-1] (a) The Director of the Institute shall (1) establish the National Diabetes Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with diabetes, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing diabetes, and (2) establish the National Diabetes Information Clearinghouse to facilitate and enhance knowledge and understanding of diabetes on the part of health professionals, patients, and the public through the effective dissemination of information.

(b) The Director of the Institute shall (1) establish the National Digestive Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with digestive diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing digestive diseases, and (2) establish the National Digestive Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of digestive diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

(c) The Director of the Institute shall (1) establish the National Kidney and Urologic Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with kidney and urologic diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing kidney and uro-

logic diseases, and (2) establish the National Kidney and Urologic Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of kidney and urologic diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

DIVISION DIRECTORS FOR DIABETES, ENDOCRINOLOGY, AND METABOLIC DISEASES, DIGESTIVE DISEASES AND NUTRITION, AND KIDNEY, UROLOGIC, AND HEMATOLOGIC DISEASES

SEC. 428. [285c-2] (a)(1) In the Institute there shall be a Division Director for Diabetes, Endocrinology, and Metabolic Diseases, a Division Director for Digestive Diseases and Nutrition, and a Division Director for Kidney, Urologic, and Hematologic Diseases. Such Division Directors, under the supervision of the Director of the Institute, shall be responsible for—

(A) developing a coordinated plan (including recommendations for expenditures) for each of the national research institutes within the National Institutes of Health with respect to research and training concerning diabetes, endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases;

(B) assessing the adequacy of management approaches for the activities within such institutes concerning such diseases and nutrition and developing improved approaches if needed;

(C) monitoring and reviewing expenditures by such institutes concerning such diseases and nutrition; and

(D) identifying research opportunities concerning such diseases and nutrition and recommending ways to utilize such opportunities.

(2) The Director of the Institute shall transmit to the Director of NIH the plans, recommendations, and reviews of the Division Directors under subparagraphs (A) through (D) of paragraph (1) together with such comments and recommendations as the Director of the Institute determines appropriate.

(b) The Director of the Institute, acting through the Division Director for Diabetes, Endocrinology, and Metabolic Diseases, the Division Director for Digestive Diseases and Nutrition, and the Division Director for Kidney, Urologic, and Hematologic Diseases, shall—

(1) carry out programs of support for research and training (other than training for which National Research Service Awards may be made under section 487) in the diagnosis, prevention, and treatment of diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

INTERAGENCY COORDINATING COMMITTEES

SEC. 429. [285c-3] (a) For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to diabetes mellitus, digestive diseases, and kidney, urologic, and hematologic diseases; and

(2) coordinating those aspects of all Federal health programs and activities relating to such diseases to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities;

the Secretary shall establish a Diabetes Mellitus Interagency Coordinating Committee, a Digestive Diseases Interagency Coordinating Committee, and a Kidney, Urologic, and Hematologic Diseases Coordinating Committee (hereafter in this section individually referred to as a "Committee").

(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research with respect to the diseases for which the Committee is established, the Division Director of the Institute for the diseases for which the Committee is established, the Chief Medical Director of the Veterans' Administration,¹ and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers) and shall include representation from all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

(c) Each Committee shall prepare an annual report for—

(1) the Secretary;

(2) the Director of NIH; and

(3) the Advisory Board established under section 430 for the diseases for which the Committee was established, detailing the work of the Committee in carrying out paragraphs (1) and (2) of subsection (a) in the fiscal year for which the report was prepared. Such report shall be submitted not later than 120 days after the end of each fiscal year.

ADVISORY BOARDS

SEC. 430. [285c-4] (a) The Secretary shall establish in the Institute the National Diabetes Advisory Board, the National Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases Advisory Board (hereafter in this section individually referred to as an "Advisory Board").

(b) Each Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to the

¹The reference is deemed to be a reference to the Under Secretary for Health of the Department of Veterans Affairs. See section 302(e)(1) of Public Law 102-405 (106 Stat. 1985) and section 10(4) of Public Law 100-527 (102 Stat. 2641).

diseases with respect to which the Advisory Board is established; and

(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in the fields of health education, nursing, data systems, public information, and community program development.

(2)(A) The following shall be ex officio members of each Advisory Board:

(i) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, the Director of the Centers for Disease Control and Prevention, the Chief Medical Director of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs, and the Division Director of the National Institute of Diabetes and Digestive and Kidney Diseases for the diseases for which the Board is established (or the designees of such officers).

(ii) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(B) In the case of the National Diabetes Advisory Board, the following shall also be ex officio members: The Director of the National Heart, Lung, and Blood Institute, the Director of the National Eye Institute, the Director of the National Institute of Child Health and Human Development, and the Administrator of the Health Resources and Services Administration (or the designees of such officers).

(c) Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

(d) The term of office of an appointed member of an Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in an Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

(e) The members of each Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of an Advisory Board, provide the Advisory Board with an executive director and one other profes-

sional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) Each Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board shall—

(1) review and evaluate the implementation of the plan (referred to in section 433) respecting the diseases with respect to which the Advisory Board was established and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting such diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan, the coordinating committee for such diseases, and with key non-Federal entities involved in activities affecting the control of such diseases.

(i) In carrying out its functions, each Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) Each Advisory Board shall prepare an annual report for the Secretary which—

(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the diseases with respect to which the Advisory Board was established;

(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year; and

(4) contains the Advisory Board's recommendations (if any) for changes in the plan referred to in section 433.

(k) The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Boards established under subsection (a) before the expiration of 90 days after

such date. The members of the Boards in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Boards established under subsection (a) for diabetes and digestive diseases, except that at least one-half of the members of the National Diabetes Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall be appointed to the National Diabetes Advisory Board first established under subsection (a).

RESEARCH AND TRAINING CENTERS

SEC. 431. [285c-5] (a)(1) Consistent with applicable recommendations of the National Commission on Diabetes, the Director of the Institute shall provide for the development or substantial expansion of centers for research and training in diabetes mellitus and related endocrine and metabolic diseases. Each center developed or expanded under this subsection shall—

(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Secretary; and

(B) conduct—

(i) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic diseases and the complications resulting from such diseases;

(ii) training programs for physicians and allied health personnel in current methods of diagnosis and treatment of such diseases and complications, and in research in diabetes; and

(iii) information programs for physicians and allied health personnel who provide primary care for patients with such diseases or complications.

(2) A center may use funds provided under paragraph (1) to provide stipends for nurses and allied health professionals enrolled in research training programs described in paragraph (1)(B)(ii).

(b) Consistent with applicable recommendations of the National Digestive Diseases Advisory Board, the Director shall provide for the development or substantial expansion of centers for research in digestive diseases and related functional, congenital, metabolic disorders, and normal development of the digestive tract. Each center developed or expanded under this subsection—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of digestive diseases and nutritional disorders and related functional, congenital, or metabolic complications resulting from such diseases or disorders;

(3) shall encourage research into and programs for—

(A) providing information for patients with such diseases and the families of such patients, physicians and others who care for such patients, and the general public;

(B) model programs for cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases, disorders, and complications; and

(4) may perform research and participate in epidemiological studies and data collection relevant to digestive diseases and disorders and disseminate such research, studies, and data to the health care profession and to the public.

(c) The Director shall provide for the development or substantial expansion of centers for research in kidney and urologic diseases. Each center developed or expanded under this subsection—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of kidney and urologic diseases;

(3) shall encourage research into and programs for—

(A) providing information for patients with such diseases, disorders, and complications and the families of such patients, physicians and others who care for such patients, and the general public;

(B) model programs for cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases; and

(4) may perform research and participate in epidemiological studies and data collection relevant to kidney and urologic diseases in order to disseminate such research, studies, and data to the health care profession and to the public.

(d)(1) The Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the development or substantial expansion of centers for research and training regarding nutritional disorders, including obesity.

(2) The Director of the Institute shall carry out paragraph (1) in collaboration with the Director of the National Cancer Institute and with the Directors of such other agencies of the National Institutes of Health as the Director of NIH determines to be appropriate.

(3) Each center developed or expanded under paragraph (1) shall—

(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director;

(B) conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of nutritional disorders, including obesity and the impact of nutrition and diet on child development;

(C) conduct training programs for physicians and allied health professionals in current methods of diagnosis and treatment of such diseases and complications, and in research in such disorders; and

(D) conduct information programs for physicians and allied health professionals who provide primary care for patients with such disorders or complications.

(e) Insofar as practicable, centers developed or expanded under this section should be geographically dispersed throughout the United States and in environments with proven research capabilities. Support of a center under this section may be for a period of not to exceed five years and such period may be extended by the Director of the Institute for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

ADVISORY COUNCIL SUBCOMMITTEES

SEC. 432. [285c-6] There are established within the advisory council for the Institute appointed under section 406 a subcommittee on diabetes and endocrine and metabolic diseases, a subcommittee on digestive diseases and nutrition, and a subcommittee on kidney, urologic, and hematologic diseases. The subcommittees shall be composed of members of the advisory council who are outstanding in the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and members of the advisory council who are leaders in the fields of education and public affairs. The subcommittees are authorized to review applications made to the Director of the Institute for grants for research and training projects relating to the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and shall recommend to the advisory council those applications and contracts that the subcommittees determine will best carry out the purposes of the Institute. The subcommittees shall also review and evaluate the diabetes and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases programs of the Institute and recommend to the advisory council such changes in the administration of such programs as the subcommittees determine are necessary.

BIENNIAL REPORT

SEC. 433. [285c-7] The Director of the Institute shall prepare for inclusion in the biennial report made under section 407 a description of the Institute's activities—

(1) under the current diabetes plan under the National Diabetes Mellitus Research and Education Act; and

(2) under the current digestive diseases plan formulated under the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976.

The description submitted by the Director shall include an evaluation of the activities of the centers supported under section 431.

NUTRITIONAL DISORDERS PROGRAM

SEC. 434. [285c-8] (a) The Director of the Institute, in consultation with the Director of NIH, shall establish a program of conducting and supporting research, training, health information

dissemination, and other activities with respect to nutritional disorders, including obesity.

(b) In carrying out the program established under subsection (a), the Director of the Institute shall conduct and support each of the activities described in such subsection.

(c) In carrying out the program established under subsection (a), the Director of the Institute shall carry out activities to facilitate and enhance knowledge and understanding of nutritional disorders, including obesity, on the part of health professionals, patients, and the public through the effective dissemination of information.

Subpart 4—National Institute of Arthritis and Musculoskeletal and Skin Diseases

PURPOSE OF THE INSTITUTE

SEC. 435. [285d] The general purpose of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (hereafter in this subpart referred to as the "Institute") is the conduct and support of research and training, the dissemination of health information, and other programs with respect to arthritis and musculoskeletal and skin diseases (including sports-related disorders), with particular attention to the effect of these diseases on children.

NATIONAL ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES PROGRAM

SEC. 436. [285d-1] (a) The Director of the Institute, with the advice of the Institute's advisory council, shall prepare and transmit to the Director of NIH a plan for a national arthritis and musculoskeletal and skin diseases program to expand, intensify, and coordinate the activities of the Institute respecting arthritis and musculoskeletal and skin diseases. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The plan shall place particular emphasis upon expanding research into better understanding the causes and the development of effective treatments for arthritis affecting children. The Director of the Institute shall periodically review and revise such plan and shall transmit any revisions of such plan to the Director of NIH.

(b) Activities under the national arthritis and musculoskeletal and skin diseases program shall be coordinated with the other national research institutes to the extent that such institutes have responsibilities respecting arthritis and musculoskeletal and skin diseases, and shall, at least, provide for—

(1) investigation into the epidemiology, etiology, and prevention of all forms of arthritis and musculoskeletal and skin diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important knowledge to the treatment and understanding of arthritis and musculoskeletal and skin diseases;

(2) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treat-

ment, including medical rehabilitation, and prevention of arthritis and musculoskeletal and skin diseases;

(3) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute for damaged bone, muscle, and joints and other supporting structures;

(4) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields; and

(5) research into the causes of arthritis affecting children and the development, trial, and evaluation of techniques, drugs and devices used in the diagnosis, treatment (including medical rehabilitation), and prevention of arthritis in children.

(c) The Director of the Institute shall carry out the national arthritis and musculoskeletal and skin diseases program in accordance with the plan prepared under subsection (a) and any revisions of such plan made under such subsection.

RESEARCH AND TRAINING

SEC. 437. [285d-2] The Director of the Institute shall—

(1) carry out programs of support for research and training (other than training for which National Research Service Awards may be made under section 487) in the diagnosis, prevention, and treatment of arthritis and musculoskeletal and skin diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

DATA SYSTEM AND INFORMATION CLEARINGHOUSE

SEC. 438. [285d-3] (a) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with arthritis and musculoskeletal and skin diseases, including where possible, data involving general populations for the purpose of detection of individuals with a risk of developing arthritis and musculoskeletal and skin diseases.

(b) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of arthritis and musculoskeletal and skin diseases by health professionals, patients, and the public.

INTERAGENCY COORDINATING COMMITTEES

SEC. 439. [285d-4] (a) For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to arthritis, musculoskeletal diseases, and skin diseases, including sports-related disorders; and

(2) coordinating the aspects of all Federal health programs and activities relating to arthritis, musculoskeletal diseases, and skin diseases in order to assure the adequacy and technical soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities,

the Secretary shall establish an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and a Skin Diseases Interagency Coordinating Committee (hereafter in this section individually referred to as a "Committee").

(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the Chief Medical Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and representatives of all other Federal departments and agencies (as determined by the Secretary) whose programs involve health functions or responsibilities relevant to arthritis and musculoskeletal diseases or skin diseases, as the case may be. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

(c) Not later than 120 days after the end of each fiscal year, each Committee shall prepare and transmit to the Secretary, the Director of NIH, the Director of the Institute, and the advisory council for the Institute a report detailing the activities of the Committee in such fiscal year in carrying out paragraphs (1) and (2) of subsection (a).

ARTHRITIS AND MUSCULOSKELETAL DISEASES DEMONSTRATION PROJECTS

SEC. 440. [285d-5] (a) The Director of the Institute may make grants to public and private nonprofit entities to establish and support projects for the development and demonstration of methods for screening, detection, and referral for treatment of arthritis and musculoskeletal diseases and for the dissemination of information on such methods to the health and allied health professions. Activities under such projects shall be coordinated with Federal, State, local, and regional health agencies, centers assisted under section 441, and the data system established under subsection (c).

(b) Projects supported under this section shall include—

(1) programs which emphasize the development and demonstration of new and improved methods of screening and early detection, referral for treatment, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) programs which emphasize the development and demonstration of new and improved methods for patient referral from local hospitals and physicians to appropriate centers for early diagnosis and treatment;

(3) programs which emphasize the development and demonstration of new and improved means of standardizing patient data and recordkeeping;

(4) programs which emphasize the development and demonstration of new and improved methods of dissemination of knowledge about the programs, methods, and means referred to in paragraphs (1), (2), and (3) of this subsection to health and allied health professionals;

(5) programs which emphasize the development and demonstration of new and improved methods for the dissemination to the general public of information—

(A) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(B) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive treatment, and control methods for arthritis and unapproved and ineffective drugs and devices for arthritis and musculoskeletal diseases; and

(6) projects for investigation into the epidemiology of all forms and aspects of arthritis and musculoskeletal diseases, including investigations into the social, environmental, behavioral, nutritional, and genetic determinants and influences involved in the epidemiology of arthritis and musculoskeletal diseases.

(c) The Director shall provide for the standardization of patient data and recordkeeping for the collection, storage, analysis, retrieval, and dissemination of such data in cooperation with projects assisted under this section, centers assisted under section 441, and other persons engaged in arthritis and musculoskeletal disease programs.

MULTIPURPOSE ARTHRITIS AND MUSCULOSKELETAL DISEASES CENTERS

SEC. 441. [285d-6] (a) The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including staffing and other operating costs such as the costs of patient care required for research) of new and existing centers for arthritis and musculoskeletal diseases. For purposes of this section, the term "modernization" means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

(b) Each center assisted under this section shall—

(1)(A) use the facilities of a single institution or a consortium of cooperating institutions, and (B) meet such qualifications as may be prescribed by the Secretary; and

(2) conduct—

(A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of and rehabilitation from arthritis and musculoskeletal diseases and complications resulting from arthritis and musculoskeletal diseases, including research into implantable

biomaterials and biomechanical and other orthopedic procedures;

(B) training programs for physicians, scientists, and other health and allied health professionals;

(C) information and continuing education programs for physicians and other health and allied health professionals who provide care for patients with arthritis and musculoskeletal diseases; and

(D) programs for the dissemination to the general public of information—

(i) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(ii) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods and unapproved and ineffective drugs and devices.

A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in paragraph (2)(B).

(c) Each center assisted under this section may conduct programs to—

(1) establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping; and

(3) develop community consultative services to facilitate the referral of patients to centers for treatment.

(d) The Director of the Institute shall, insofar as practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of children affected by arthritis and musculoskeletal diseases.

(e) Support of a center under this section may be for a period of not to exceed five years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(f) Not later than October 1, 1993, the Director shall establish a multipurpose arthritis and musculoskeletal disease center for the purpose of expanding the level of research into the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculoskeletal diseases.

ADVISORY BOARD

SEC. 442. [285d-7] (a) The Secretary shall establish in the Institute the National Arthritis and Musculoskeletal and Skin Diseases Advisory Board (hereafter in this section referred to as the "Advisory Board").

(b) The Advisory Board shall be composed of twenty appointed members and nonvoting, ex officio members, as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to arthritis, musculoskeletal diseases, and skin diseases; and

(B) eight members from the general public who are knowledgeable with respect to such diseases, including one member who is a person who has such a disease, one person who is the parent of an adult with such a disease, and two members who are parents of children with arthritis.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in health education, nursing, data systems, public information, or community program development.

(2) The following shall be ex officio members of the Advisory Board:

(A) the Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Director of the Centers for Disease Control and Prevention, the Chief Medical Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(c) Members of the Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Advisory Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Advisory Board.

(d) The term of office of an appointed member of the Advisory Board is four years. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

(e) The members of the Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through

contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) The Advisory Board shall—

(1) review and evaluate the implementation of the plan prepared under section 436(a) and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting arthritis, musculoskeletal diseases and skin diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies for Federal agencies involved in the implementation of such plan, the interagency coordinating committees for such diseases established under section 439, and with key non-Federal entities involved in activities affecting the control of such diseases.

(i) In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) The Advisory Board shall prepare an annual report for the Secretary which—

(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to arthritis, musculoskeletal diseases, and skin diseases;

(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year for which the report is made;

(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 436(a); and

(5) contains recommendations for expanding the Institute's funding of research directly applicable to the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculoskeletal diseases.

(k) The National Arthritis Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Board established under subsection (a) before the expiration of 90 days after such date. The members of the Board in existence

on such date may be appointed, in accordance with subsections (b) and (d), to the Advisory Board established under subsection (a).

Subpart 5—National Institute on Aging

PURPOSE OF THE INSTITUTE

SEC. 443. [285e] The general purpose of the National Institute on Aging (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical, social, and behavioral research, training, health information dissemination, and other programs with respect to the aging process and the diseases and other special problems and needs of the aged.

SPECIAL FUNCTIONS

SEC. 444. [285e-1] (a) In carrying out the training responsibilities under this Act or any other Act for health and allied health professions personnel, the Secretary shall take appropriate steps to insure the education and training of adequate numbers of allied health, nursing, and paramedical personnel in the field of health care for the aged.

(b) The Director of the Institute shall conduct scientific studies to measure the impact on the biological, medical, social, and psychological aspects of aging of programs and activities assisted or conducted by the Department of Health and Human Services.

(c) The Director of the Institute shall carry out public information and education programs designed to disseminate as widely as possible the findings of research sponsored by the Institute, other relevant aging research and studies, and other information about the process of aging which may assist elderly and near-elderly persons in dealing with, and all Americans in understanding, the problems and processes associated with growing older.

(d) The Director of the Institute shall make grants to public and private nonprofit institutions to conduct research relating to Alzheimer's Disease.

ALZHEIMER'S DISEASE CENTERS

SEC. 445. [285e-2] (a)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities (including university medical centers) to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support (including staffing) for centers for basic and clinical research (including multidisciplinary research) into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for Alzheimer's disease.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(b)(1) Federal payments made under a cooperative agreement or grant under subsection (a) may, with respect to Alzheimer's disease, be used for—

(A) diagnostic examinations, patient assessments, patient care costs, and other costs necessary for conducting research;

(B) training, including training for allied health professionals;

(C) diagnostic and treatment clinics designed to meet the special needs of minority and rural populations and other underserved populations;

(D) activities to educate the public; and

(E) the dissemination of information.

(2) For purposes of paragraph (1), the term "training" does not include research training for which National Research Service Awards may be provided under section 487.

(c) Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

CLAUDE D. PEPPER OLDER AMERICANS INDEPENDENCE CENTERS

SEC. 445A. [285e-3] (a) The Director of the Institute shall enter into cooperative agreements with, and make grants to, public and private nonprofit entities for the development or expansion of not less than 10 centers of excellence in geriatric research and training of researchers. Each such center shall be known as a Claude D. Pepper Older Americans Independence Center.

(b) Each center developed or expanded under this section shall—

(1) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director; and

(2) conduct—

(A) research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause, which research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals; and

(B) programs to develop individuals capable of conducting research described in subparagraph (A).

(c) In making cooperative agreements and grants under this section for the development or expansion of centers, the Director of the Institute shall ensure that, to the extent practicable, any such centers are distributed equitably among the principal geographic regions of the United States.

(d) For purposes of this section, the term "independence", with respect to diseases, disorders, and complications of aging, means the functional ability of individuals to perform activities of daily living or instrumental activities of daily living without assistance or supervision.

AWARDS AUTHORIZED

SEC. 445B.¹ [285e-4] (a) The Director of the Institute shall make awards to senior researchers who have made distinguished achievements in biomedical research in areas relating to Alzheimer's disease and related dementias. Awards under this section shall be used by the recipients to support research in areas relating to such disease and dementias, and may be used by the recipients to train junior researchers who demonstrate exceptional promise to conduct research in such areas.

(b) The Director of the Institute may make awards under this section to researchers at centers supported under section 445 and to researchers at other public and nonprofit private entities.

(c) The Director of the Institute shall make awards under this section only to researchers who have been recommended for such awards by the National Advisory Council on Aging.

(d) The Director of the Institute shall establish procedures for the selection of the recipients of awards under this section.

(e) Awards under this section shall be made for a one-year period, and may be renewed for not more than six additional consecutive one-year periods.

RESEARCH PROGRAM AND PLAN

SEC. 445C. [285e-5] (a) The Director of the Institute shall conduct, or make grants for the conduct of, research relevant to appropriate services for individuals with Alzheimer's disease and related dementias and their families.

(b)(1) Within 6 months after the date of enactment of the Alzheimer's Disease and Related Dementias Services Research Act of 1986, the Director of the Institute shall prepare and transmit to the Chairman of the Council on Alzheimer's Disease (in this section referred to as the "Council") a plan for the research to be conducted under subsection (a). The plan shall—

(A) provide for research concerning—

(i) the epidemiology of, and the identification of risk factors for, Alzheimer's disease and related dementias; and

(ii) the development and evaluation of reliable and valid multidimensional diagnostic and assessment procedures and instruments; and

(B) ensure that research carried out under the plan is coordinated with, and uses, to the maximum extent feasible, resources of, other Federal programs relating to Alzheimer's disease and related dementias, including centers supported under section 445, centers supported by the National Institute of Mental Health on the psychopathology of the elderly, relevant activities of the Administration on Aging, other programs and centers involved in research on Alzheimer's disease and related dementias supported by the Department, and other programs relating to Alzheimer's disease and related dementias which are planned or conducted by Federal agencies other than the

¹ Sections 445B through 445F were originally enacted as provisions of title IX of Public Law 99-660, and were transferred to the Public Health Service Act by section 142 of Public Law 100-607. (Various provisions relating to Alzheimer's disease remain in such title IX, which is included in this compilation.)

Department, State or local agencies, community organizations, or private foundations.

(2) Within one year after transmitting the plan required under paragraph (1), and annually thereafter, the Director of the Institute shall prepare and transmit to the Chairman of the Council such revisions of such plan as the Director considers appropriate.

(c) In preparing and revising the plan required by subsection (b), the Director of the Institute shall consult with the Chairman of the Council and the heads of agencies within the Department.

(d) the¹ Director of the Institute may develop, or make grants to develop—

(1) model techniques to—

(A) promote greater independence, including enhanced independence in performing activities of daily living and instrumental activities of daily living, for persons with Alzheimer's disease and related disorders; and

(B) prevent or reduce the severity of secondary disabilities, including confusional episodes, falls, bladder and bowel incontinence, and adverse effects of prescription and over-the-counter medications, in such persons; and

(2) model curricula for health care professionals, health care paraprofessionals, and family caregivers, for training and application in the use of such techniques.

(e) For purposes of this section, the term "Council on Alzheimer's Disease" means the council established in section 911(a) of Public Law 99-660.

DISSEMINATION

SEC. 445D. [285e-6] The Director of the Institute shall disseminate the results of research conducted under section 445C and this section to appropriate professional entities and to the public.

CLEARINGHOUSE ON ALZHEIMER'S DISEASE

SEC. 445E. [285e-7] (a) The Director of the Institute shall establish the Clearinghouse on Alzheimer's Disease (hereinafter referred to as the "Clearinghouse"). The purpose of the Clearinghouse is the dissemination of information concerning services available for individuals with Alzheimer's disease and related dementias and their families. The Clearinghouse shall—

(1) compile, archive, and disseminate information concerning research, demonstration, evaluation, and training programs and projects concerning Alzheimer's disease and related dementias; and

(2) annually publish a summary of the information compiled under paragraph (1) during the preceding 12-month period, and make such information available upon request to appropriate individuals and entities, including educational institutions, research entities, and Federal and public agencies.

¹ So in law. See section 9 of Public Law 102-507 (106 Stat. 3287). Probably should be "The".

(b) The Clearinghouse may charge an appropriate fee for information provided through the toll-free telephone line established under subsection (a)(3).¹

(c) The Director of the Institute, the Director of the National Institute of Mental Health, and the Director of the National Center for Health Services Research and Health Care Technology Assessment shall provide to the Clearinghouse summaries of the findings of research conducted under part D.

DISSEMINATION PROJECT

SEC. 445F. [285e-8] (a) The Director of the Institute shall make a grant to, or enter into a contract with, a national organization representing individuals with Alzheimer's disease and related dementias for the conduct of the activities described in subsection (b).

(b) The organization receiving a grant or contract under this section shall—

(1) establish a central computerized information system to—

(A) compile and disseminate information concerning initiatives by State and local governments and private entities to provide programs and services for individuals with Alzheimer's disease and related dementias; and

(B) translate scientific and technical information concerning such initiatives into information readily understandable by the general public, and make such information available upon request; and

(2) establish a national toll-free telephone line to make available the information described in paragraph (1), and information concerning Federal programs, services and benefits for individuals with Alzheimer's disease and related dementias and their families.

(c) The organization receiving a grant or contract under this section may charge appropriate fees for information provided through the toll-free telephone line established under subsection (b)(2), and may make exceptions to such fees for individuals and organizations who are not financially able to pay such fees.

(d) In order to receive a grant or contract under this section, an organization shall submit an application to the Director of the Institute. Such application shall contain—

(1) information demonstrating that such organization has a network of contacts which will enable such organization to receive information necessary to the operation of the central computerized information system described in subsection (b)(1);

(2) information demonstrating that, by the end of fiscal year 1991, such organization will be financially able to, and will, carry out the activities described in subsection (b) without a grant or contract from the Federal Government; and

(3) such other information as the Director may prescribe.

¹ So in original. Section 445E does not contain a subsection (a)(3). Section 445F(b)(2) provides for a toll-free telephone line.

ALZHEIMER'S DISEASE REGISTRY

SEC. 445G. [285e-9] (a) IN GENERAL.—The Director of the Institute may make a grant to develop a registry for the collection of epidemiological data about Alzheimer's disease and its incidence in the United States, to train personnel in the collection of such data, and for other matters respecting such disease.

(b) QUALIFICATIONS.—To qualify for a grant under subsection (a) an applicant shall—

(1) be an accredited school of medicine or public health which has expertise in the collection of epidemiological data about individuals with Alzheimer's disease and in the development of disease registries, and

(2) have access to a large patient population, including a patient population representative of diverse ethnic backgrounds.

AGING PROCESSES REGARDING WOMEN

SEC. 445H. [285e-10] The Director of the Institute, in addition to other special functions specified in section 444 and in cooperation with the Directors of the other national research institutes and agencies of the National Institutes of Health, shall conduct research into the aging processes of women, with particular emphasis given to the effects of menopause and the physiological and behavioral changes occurring during the transition from pre- to post-menopause, and into the diagnosis, disorders, and complications related to aging and loss of ovarian hormones in women.

AUTHORIZATION OF APPROPRIATIONS

SEC. 445I. [285e-11] For the purpose of carrying out this subpart, there are authorized to be appropriated \$500,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

Subpart 6—National Institute of Allergy and Infectious Diseases

PURPOSE OF THE INSTITUTE

SEC. 446. [285f] The general purpose of the National Institute of Allergy and Infectious Diseases is the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases, including tropical diseases.

RESEARCH AND RESEARCH TRAINING REGARDING TUBERCULOSIS

SEC. 447. [285f-2] (a) In carrying out section 446, the Director of the Institute shall conduct or support research and research training regarding the cause, diagnosis, early detection, prevention and treatment of tuberculosis.

(b) For the purpose of carrying out subsection (a), there are authorized to be appropriated \$50,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998. Such authorization is in addition to any other authorization of appropriations that is available for such purpose.

RESEARCH CENTERS REGARDING CHRONIC FATIGUE SYNDROME

SEC. 447. ¹ [285f-1] (a) The Director of the Institute, after consultation with the advisory council for the Institute, may make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct basic and clinical research on chronic fatigue syndrome.

(b) Each center assisted under this section shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

Subpart 7—National Institute of Child Health and Human Development

PURPOSE OF THE INSTITUTE

SEC. 448. [285g] The general purpose of the National Institute of Child Health and Human Development (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to maternal health, child health, mental retardation, human growth and development, including prenatal development, population research, and special health problems and requirements of mothers and children.

SUDDEN INFANT DEATH SYNDROME

SEC. 449. [285g-1] The Director of the Institute shall conduct and support research which specifically relates to sudden infant death syndrome.

MENTAL RETARDATION RESEARCH

SEC. 450. [285g-2] The Director of the Institute shall conduct and support research and related activities into the causes, prevention, and treatment of mental retardation.

ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 451. [285g-3] (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of health problems of mothers and children. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

NATIONAL CENTER FOR MEDICAL REHABILITATION RESEARCH

SEC. 452. [285g-4] (a) There shall be in the Institute an agency to be known as the National Center for Medical Rehabilitation

¹ There are two sections 447 in the law. See section 902 of Public Law 103-43 (107 Stat. 164) and section 302 of Public Law 103-183 (107 Stat. 2235).

Research (hereafter in this section referred to as the "Center")¹. The Director of the Institute shall appoint a qualified individual to serve as Director of the Center. The Director of the Center shall report directly to the Director of the Institute.

(b) The general purpose of the Center is the conduct and support of research and research training (including research on the development of orthotic and prosthetic devices), the dissemination of health information, and other programs with respect to the rehabilitation of individuals with physical disabilities resulting from diseases or disorders of the neurological, musculoskeletal, cardiovascular, pulmonary, or any other physiological system (hereafter in this section referred to as "medical rehabilitation").

(c)(1) In carrying out the purpose described in subsection (b), the Director of the Center may—

(A) provide for clinical trials regarding medical rehabilitation;

(B) provide for research regarding model systems of medical rehabilitation;

(C) coordinate the activities of the Center with similar activities of other agencies of the Federal Government, including the other agencies of the National Institutes of Health, and with similar activities of other public entities and of private entities;

(D) support multidisciplinary medical rehabilitation research conducted or supported by more than one such agency;

(E) in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

(i) establish technical and scientific peer review groups in addition to those appointed under section 402(b)(6); and

(ii) appoint the members of peer review groups established under subparagraph (A); and

(F) support medical rehabilitation research and training centers.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under subparagraph (E).

(2) In carrying out this section, the Director of the Center may make grants and enter into cooperative agreements and contracts.

(d)(1) In consultation with the Director of the Center, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), the Director of the Institute shall develop a comprehensive plan for the conduct and support of medical rehabilitation research (hereafter in this section referred to as the "Research Plan").

(2) The Research Plan shall—

(A) identify current medical rehabilitation research activities conducted or supported by the Federal Government, opportunities and needs for additional research, and priorities for such research; and

¹Section 3(b) of Public Law 101-613 requires that Federal agencies, as appropriate, enter into agreements for preventing duplication among Federal programs regarding medical rehabilitation. Such section requires that the agreements be made not later than one year after the date of the enactment of the Public Law, which was enacted November 16, 1990.

(B) make recommendations for the coordination of such research conducted or supported by the National Institutes of Health and other agencies of the Federal Government.

(3)(A) Not later than 18 months after the date of the enactment of the National Institutes of Health Revitalization Amendments of 1990,¹ the Director of the Institute shall transmit the Research Plan to the Director of NIH, who shall submit the Plan to the President and the Congress.

(B) Subparagraph (A) shall be carried out independently of the process of reporting that is required in sections 403 and 407.

(4) The Director of the Institute shall periodically revise and update the Research Plan as appropriate, after consultation with the Director of the Center, the coordinating committee established under subsection (e), and the advisory board established under subsection (f). A description of any revisions in the Research Plan shall be contained in each report prepared under section 407 by the Director of the Institute.

(e)(1) The Director of NIH shall establish a committee to be known as the Medical Rehabilitation Coordinating Committee (hereafter in this section referred to as the "Coordinating Committee").

(2) The Coordinating Committee shall make recommendations to the Director of the Institute and the Director of the Center with respect to the content of the Research Plan and with respect to the activities of the Center that are carried out in conjunction with other agencies of the National Institutes of Health and with other agencies of the Federal Government.

(3) The Coordinating Committee shall be composed of the Director of the Center, the Director of the Institute, and the Directors of the National Institute on Aging, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Heart, Lung, and Blood Institute, the National Institute of Neurological Disorders and Stroke, and such other national research institutes and such representatives of other agencies of the Federal Government as the Director of NIH determines to be appropriate.

(4) The Coordinating Committee shall be chaired by the Director of the Center.

(f)(1) Not later than 90 days after the date of the enactment of the National Institutes of Health Revitalization Amendments of 1990,¹ the Director of NIH shall establish a National Advisory Board on Medical Rehabilitation Research (hereafter in this section referred to as the "Advisory Board").

(2) The Advisory Board shall review and assess Federal research priorities, activities, and findings regarding medical rehabilitation research, and shall advise the Director of the Center and the Director of the Institute on the provisions of the Research Plan.

(3)(A) The Director of NIH shall appoint to the Advisory Board 18 qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, 12 shall be representatives of health and scientific disciplines with respect

¹So in original. No Act with such a short title was enacted during 1990. The probable intent of the Congress was to make a reference to Public Law 101-613, the National Institutes of Health Amendments of 1990, which added section 452 and which was enacted November 16, 1990.

to medical rehabilitation and 6 shall be individuals representing the interests of individuals undergoing, or in need of, medical rehabilitation.

(B) The following officials shall serve as ex officio members of the Advisory Board:

- (i) The Director of the Center.
- (ii) The Director of the Institute.
- (iii) The Director of the National Institute on Aging.
- (iv) The Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.
- (v) The Director of the National Institute on Deafness and Other Communication Disorders.
- (vi) The Director of the National Heart, Lung, and Blood Institute.
- (vii) The Director of the National Institute of Neurological Disorders and Stroke.
- (viii) The Director of the National Institute on Disability and Rehabilitation Research.
- (ix) The Commissioner for Rehabilitation Services Administration.
- (x) The Assistant Secretary of Defense (Health Affairs).
- (xi) The Chief Medical Director of the Department of Veterans Affairs.

(4) The members of the Advisory Board shall, from among the members appointed under paragraph (3)(A), designate an individual to serve as the chair of the Advisory Board.

RESEARCH CENTERS WITH RESPECT TO CONTRACEPTION AND INFERTILITY

SEC. 452A. [285g-5] (a) The Director of the Institute, after consultation with the advisory council for the Institute, shall make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct activities for the purpose of improving methods of contraception and centers to conduct activities for the purpose of improving methods of diagnosis and treatment of infertility.

(b) In carrying out subsection (a), the Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the establishment of three centers with respect to contraception and for two centers with respect to infertility.

(c)(1) Each center assisted under this section shall, in carrying out the purpose of the center involved—

(A) conduct clinical and other applied research, including—

(i) for centers with respect to contraception, clinical trials of new or improved drugs and devices for use by males and females (including barrier methods); and

(ii) for centers with respect to infertility, clinical trials of new or improved drugs and devices for the diagnosis and treatment of infertility in males and females;

(B) develop protocols for training physicians, scientists, nurses, and other health and allied health professionals;

(C) conduct training programs for such individuals;

(D) develop model continuing education programs for such professionals; and

(E) disseminate information to such professionals and the public.

(2) A center may use funds provided under subsection (a) to provide stipends for health and allied health professionals enrolled in programs described in subparagraph (C) of paragraph (1), and to provide fees to individuals serving as subjects in clinical trials conducted under such paragraph.

(d) The Director of the Institute shall, as appropriate, provide for the coordination of information among the centers assisted under this section.

(e) Each center assisted under subsection (a) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

(f) Support of a center under subsection (a) may be for a period not exceeding 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(g) For the purpose of carrying out this section, there are authorized to be appropriated \$30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

SEC. 452B. [285g-6] The Director of the Institute shall establish and maintain within the Institute an intramural laboratory and clinical research program in obstetrics and gynecology.

CHILD HEALTH RESEARCH CENTERS

SEC. 452C. [285g-7] The Director of the Institute shall develop and support centers for conducting research with respect to child health. Such centers shall give priority to the expeditious transfer of advances from basic science to clinical applications and improving the care of infants and children.

PROSPECTIVE LONGITUDINAL STUDY ON ADOLESCENT HEALTH

SEC. 452D. [285g-8] (a) IN GENERAL.—Not later than October 1, 1993, the Director of the Institute shall commence a study for the purpose of providing information on the general health and well-being of adolescents in the United States, including, with respect to such adolescents, information on—

(1) the behaviors that promote health and the behaviors that are detrimental to health; and

(2) the influence on health of factors particular to the communities in which the adolescents reside.

(b) DESIGN OF STUDY.—

(1) IN GENERAL.—The study required in subsection (a) shall be a longitudinal study in which a substantial number of

adolescents participate as subjects. With respect to the purpose described in such subsection, the study shall monitor the subjects throughout the period of the study to determine the health status of the subjects and any change in such status over time.

(2) **POPULATION-SPECIFIC ANALYSES.**—The study required in subsection (a) shall be conducted with respect to the population of adolescents who are female, the population of adolescents who are male, various socioeconomic populations of adolescents, and various racial and ethnic populations of adolescents. The study shall be designed and conducted in a manner sufficient to provide for a valid analysis of whether there are significant differences among such populations in health status and whether and to what extent any such differences are due to factors particular to the populations involved.

(c) **COORDINATION WITH WOMEN'S HEALTH INITIATIVE.**—With respect to the national study of women being conducted by the Secretary and known as the Women's Health Initiative, the Secretary shall ensure that such study is coordinated with the component of the study required in subsection (a) that concerns adolescent females, including coordination in the design of the 2 studies.

Subpart 8—National Institute of Dental Research

PURPOSE OF THE INSTITUTE

SEC. 453. [285h] The general purpose of the National Institute of Dental Research is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, prevention, and methods of diagnosis and treatment of dental and oral diseases and conditions.

Subpart 9—National Eye Institute

PURPOSE OF THE INSTITUTE

SEC. 455. [285i] The general purpose of the National Eye Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind. Subject to section 456, the Director of the Institute may carry out a program of grants for public and private nonprofit vision research facilities.

CLINICAL RESEARCH ON EYE CARE AND DIABETES

SEC. 456. [285i-1] (a) **PROGRAM OF GRANTS.**—The Director of the Institute, in consultation with the advisory council for the Institute, may award research grants to one or more Diabetes Eye Research Institutions for the support of programs in clinical or health services aimed at—

(1) providing comprehensive eye care services for people with diabetes, including a full complement of preventive, diagnostic and treatment procedures;

(2) developing new and improved techniques of patient care through basic and clinical research;

(3) assisting in translation of the latest research advances into clinical practice; and

(4) expanding the knowledge of the eye and diabetes through further research.

(b) USE OF FUNDS.—Amounts received under a grant awarded under this section shall be used for the following:

(1) Establishing the biochemical, cellular, and genetic mechanisms associated with diabetic eye disease and the earlier detection of pending eye abnormalities. The focus of work under this paragraph shall require that ophthalmologists have training in the most up-to-date molecular and cell biological methods.

(2) Establishing new frontiers in technology, such as video-based diagnostic and research resources, to—

(A) provide improved patient care;

(B) provide for the evaluation of retinal physiology and its affect on diabetes; and

(C) provide for the assessment of risks for the development and progression of diabetic eye disease and a more immediate evaluation of various therapies aimed at preventing diabetic eye disease.

Such technologies shall be designed to permit evaluations to be performed both in humans and in animal models.

(3) The translation of the results of vision research into the improved care of patients with diabetic eye disease. Such translation shall require the application of institutional resources that encompass patient care, clinical research and basic laboratory research.

(4) The conduct of research concerning the outcomes of eye care treatments and eye health education programs as they relate to patients with diabetic eye disease, including the evaluation of regional approaches to such research.

(c) AUTHORIZED EXPENDITURES.—The purposes for which a grant under subsection (a) may be expended include equipment for the research described in such subsection.

Subpart 10—National Institute of Neurological Disorders and Stroke

PURPOSE OF THE INSTITUTE

SEC. 457. [285j] The general purpose of the National Institute of Neurological Disorders and Stroke (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to neurological disease and disorder and stroke.

SPINAL CORD REGENERATION RESEARCH

SEC. 458. [285j–7] The Director of the Institute shall conduct and support research into spinal cord regeneration.

BIOENGINEERING RESEARCH

SEC. 459. [285j-2] The Director of the Institute shall make grants or enter into contracts for research on the means to overcome paralysis of the extremities through electrical stimulation and the use of computers.

RESEARCH ON MULTIPLE SCLEROSIS

SEC. 460. [285j-3] The Director of the Institute shall conduct and support research on multiple sclerosis, especially research on effects of genetics and hormonal changes on the progress of the disease.

Subpart 11—National Institute of General Medical Sciences

PURPOSE OF THE INSTITUTE

SEC. 461. [285k] The general purpose of the National Institute of General Medical Sciences is the conduct and support of research, training, and, as appropriate, health information dissemination, and other programs with respect to general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other national research institutes or are outside the general area of responsibility of any other national research institute.

Subpart 12—National Institute of Environmental Health Sciences

PURPOSE OF THE INSTITUTE

SEC. 463. [285l] The general purpose of the National Institute of Environmental Health Sciences (in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly.

APPLIED TOXICOLOGICAL RESEARCH AND TESTING PROGRAM

SEC. 463A. [285l-1] (a) There is established within the Institute a program for conducting applied research and testing regarding toxicology, which program shall be known as the Applied Toxicological Research and Testing Program.

(b) In carrying out the program established under subsection (a), the Director of the Institute shall, with respect to toxicology, carry out activities—

(1) to expand knowledge of the health effects of environmental agents;

(2) to broaden the spectrum of toxicology information that is obtained on selected chemicals;

(3) to develop and validate assays and protocols, including alternative methods that can reduce or eliminate the use of animals in acute or chronic safety testing;

(4) to establish criteria for the validation and regulatory acceptance of alternative testing and to recommend a process through which scientifically validated alternative methods can be accepted for regulatory use;

(5) to communicate the results of research to government agencies, to medical, scientific, and regulatory communities, and to the public; and

(6) to integrate related activities of the Department of Health and Human Services.

Subpart 13—National Institute on Deafness and Other Communication Disorders

PURPOSE OF THE INSTITUTE

SEC. 464. [285m] The general purpose of the National Institute on Deafness and Other Communication Disorders (hereafter referred to in this subpart as the "Institute") is the conduct and support of research and training, the dissemination of health information, and other programs with respect to disorders of hearing and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell.

NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS PROGRAM

SEC. 464A. [285m-1] (a) The Director of the Institute, with the advice of the Institute's advisory council, shall establish a National Deafness and Other Communication Disorders Program (hereafter in this section referred to as the "Program"). The Director or the Institute shall, with respect to the Program, prepare and transmit to the Director of NIH a plan to initiate, expand, intensify and coordinate activities of the Institute respecting disorders of hearing (including tinnitus) and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Director of NIH.

(b) Activities under the Program shall include—

(1) investigation into the etiology, pathology, detection, treatment, and prevention of all forms of disorders of hearing and other communication processes, primarily through the support of basic research in such areas as anatomy, audiology, biochemistry, bioengineering, epidemiology, genetics, immunology, microbiology, molecular biology, the neurosciences, otolaryngology, psychology, pharmacology, physiology, speech and language pathology, and any other scientific disciplines that can contribute important knowledge to the understanding and elimination of disorders of hearing and other communication processes;

(2) research into the evaluation of techniques (including surgical, medical, and behavioral approaches) and devices (including hearing aids, implanted auditory and nonauditory prosthetic devices and other communication aids) used in diagnosis, treatment, rehabilitation, and prevention of disorders of hearing and other communication processes;

(3) research into prevention, and early detection and diagnosis, of hearing loss and speech and language disturbances

(including stuttering) and research into preventing the effects of such disorders on learning and learning disabilities with extension of programs for appropriate referral and rehabilitation;

(4) research into the detection, treatment, and prevention of disorders of hearing and other communication processes in the growing elderly population with extension of rehabilitative programs to ensure continued effective communication skills in such population;

(5) research to expand knowledge of the effects of environmental agents that influence hearing or other communication processes; and

(6) developing and facilitating intramural programs on clinical and fundamental aspects of disorders of hearing and all other communication processes.

DATA SYSTEM AND INFORMATION CLEARINGHOUSE

SEC. 464B. [285m-2] (a) The Director of the Institute shall establish a National Deafness and Other Communication Disorders Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with disorders of hearing or other communication processes, including where possible, data involving general populations for the purpose of identifying individuals at risk of developing such disorders.

(b) The Director of the Institute shall establish a National Deafness and Other Communication Disorders Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of disorders of hearing and other communication processes by health professionals, patients, industry, and the public.

MULTIPURPOSE DEAFNESS AND OTHER COMMUNICATION DISORDERS CENTER

SEC. 464C. [285m-3] (a) The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including care required for research) of new and existing centers for studies of disorders of hearing and other communication processes. For purposes of this section, the term "modernization" means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

(b) Each center assisted under this section shall—

(1) use the facilities of a single institution or a consortium of cooperating institutions; and

(2) meet such qualifications as may be prescribed by the Secretary.

(c) Each center assisted under this section shall, at least, conduct—

(1) basic and clinical research into the cause diagnosis, early detection, prevention, control and treatment of disorders of hearing and other communication processes and complications resulting from such disorders, including research into re-

habilitative aids, implantable biomaterials, auditory speech processors, speech production devices, and other otolaryngologic procedures;

(2) training programs for physicians, scientists, and other health and allied health professionals;

(3) information and continuing education programs for physicians and other health and allied health professionals who will provide care for patients with disorders of hearing or other communication processes; and

(4) programs for the dissemination to the general public of information—

(A) on the importance of early detection of disorders of hearing and other communication processes, of seeking prompt treatment, rehabilitation, and of following an appropriate regimen; and

(B) on the importance of avoiding exposure to noise and other environmental toxic agents that may affect disorders of hearing or other communication processes.

(d) A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in subsection (c)(2).

(e) Each center assisted under this section may conduct programs—

(1) to establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals at risk of developing disorders of hearing or other communication processes; and

(2) to disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping.

(f) The Director of the Institute shall, to the extent practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of the elderly, and of children (particularly with respect to their education and training), affected by disorders of hearing or other communication processes.

(g) Support of a center under this section may be for a period not to exceed seven years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director, with the advice of the Institute's advisory council, if such group has recommended to the Director that such period should be extended.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION
DISORDERS ADVISORY BOARD

SEC. 464D. [285m-4] (a) The Secretary shall establish in the Institute the National Deafness and Other Communications Disorders Advisory Board (hereafter in this section referred to as the "Advisory Board").

(b) The Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health and rehabilitation professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to deafness and other communication disorders, including not less than two persons with a communication disorder; and

(B) six members from the general public who are knowledgeable with respect to such disorders, including not less than one person with a communication disorder and not less than one person who is a parent of an individual with such a disorder.

Of the appointed members, not less than five shall by virtue of training or experience be knowledgeable in diagnoses and rehabilitation of communication disorders, education of the hearing, speech, or language impaired, public health, public information, community program development, occupational hazards to communications senses, or the aging process.

(2) The following shall be ex officio members of each Advisory Board:

(A) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute on Deafness and Other Communication Disorders, the Director of the Centers for Disease Control and Prevention, the Chief Medical Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers).

(B) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(c) Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

(d) The term of office of an appointed member of the Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

(e) The members of the Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after con-

sultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) The Advisory Board shall—

(1) review and evaluate the implementation of the plan prepared under section 464A(a) and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting deafness and other communication disorders, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan and with key non-Federal entities involved in activities affecting the control of such disorders.

(i) In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) The Advisory Board shall prepare an annual report for the Secretary which—

(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the deafness and other communication disorders;

(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such disorders in such fiscal year; and

(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 464A(a).

(k) The National Deafness and Other Communication Disorders Advisory Board shall be established not later than April 1, 1989.

INTERAGENCY COORDINATING COMMITTEE

SEC. 464E. [285m-5] (a) The Secretary may establish a committee to be known as the Deafness and Other Communication Disorders Interagency Coordinating Committee (hereafter in this section referred to as the "Coordinating Committee").

(b) The Coordinating Committee shall, with respect to deafness and other communication disorders—

(1) provide for the coordination of the activities of the national research institutes; and

(2) coordinate the aspects of all Federal health programs and activities relating to deafness and other communication disorders in order to assure the adequacy and technical soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities.

(c) The Coordinating Committee shall be composed of the directors of each of the national research institutes and divisions involved in research with respect to deafness and other communication disorders and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to deafness and other communication disorders.

(d) The Coordinating Committee shall be chaired by the Director of NIH (or the designee of the Director). The Committee shall meet at the call of the chair, but not less often than four times a year.

(e) Not later than 120 days after the end of each fiscal year, the Coordinating Committee shall prepare and transmit to the Secretary, the Director of NIH, the Director of the Institute, and the advisory council for the Institute a report detailing the activities of the Committee in such fiscal year in carrying out subsection (b).

LIMITATION ON ADMINISTRATIVE EXPENSES

SEC. 464F. [285m-6] With respect to amounts appropriated for a fiscal year for the National Institutes of Health, the limitation established in section 408(a)(1) on the expenditure of such amounts for administrative expenses shall apply to administrative expenses of the National Institute on Deafness and Other Communication Disorders.

Subpart 14—National Institute on Alcohol Abuse and Alcoholism

PURPOSE OF INSTITUTE

SEC. 464H. [285n] (a) IN GENERAL.—The general purpose of the National Institute on Alcohol Abuse and Alcoholism (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of alcohol abuse and the treatment of alcoholism.

(b) RESEARCH PROGRAM.—The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of alcohol abuse and alcoholism. In carrying out the program, the Director of the Institute is authorized to—

(1) collect and disseminate through publications and other appropriate means (including the development of curriculum materials), information as to, and the practical application of, the research and other activities under the program;

(2) make available research facilities of the Public Health Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants to universities, hospitals, laboratories, and other public or nonprofit institutions, and to individuals for such research projects as are recommended by the National Advisory Council on Alcohol Abuse and Alcoholism, giving special consideration to projects relating to—

(A) the relationship between alcohol abuse and domestic violence,

(B) the effects of alcohol use during pregnancy,

(C) the impact of alcoholism and alcohol abuse on the family, the workplace, and systems for the delivery of health services,

(D) the relationship between the abuse of alcohol and other drugs,

(E) the effect on the incidence of alcohol abuse and alcoholism of social pressures, legal requirements respecting the use of alcoholic beverages, the cost of such beverages, and the economic status and education of users of such beverages,

(F) the interrelationship between alcohol use and other health problems,

(G) the comparison of the cost and effectiveness of various treatment methods for alcoholism and alcohol abuse and the effectiveness of prevention and intervention programs for alcoholism and alcohol abuse, and

(H) alcoholism and alcohol abuse among women;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) promote the coordination of research programs conducted by the Institute, and similar programs conducted by the National Institute of Drug Abuse and by other departments, agencies, organizations, and individuals, including all National Institutes of Health research activities which are or may be related to the problems of individuals suffering from alcoholism or alcohol abuse or those of their families or the impact of alcohol abuse on other health problems;

(6) conduct an intramural program of biomedical, behavioral, epidemiological, and social research, including research into the most effective means of treatment and service delivery, and including research involving human subjects, which is—

(A) located in an institution capable of providing all necessary medical care for such human subjects, including complete 24-hour medical diagnostic services by or under the supervision of physicians, acute and intensive medical care, including 24-hour emergency care, psychiatric care, and such other care as is determined to be necessary for individuals suffering from alcoholism and alcohol abuse; and

(B) associated with an accredited medical or research training institution;

(7) for purposes of study, admit and treat at institutions, hospitals, and stations of the Public Health Service, persons not otherwise eligible for such treatment;

(8) provide to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical and other scientific research methods to experiments, studies, and surveys in health and medical fields;

(9) enter into contracts under this title without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529;¹ 41 U.S.C. 5); and

(10) adopt, upon recommendation of the National Advisory Council on Alcohol Abuse and Alcoholism, such additional means as he deems necessary or appropriate to carry out the purposes of this section.

(c) **COLLABORATION.**—The Director of the Institute shall collaborate with the Administrator of the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

(d) **FUNDING.**—

(1) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this subpart, there are authorized to be appropriated \$300,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(2) **ALLOCATION FOR HEALTH SERVICES RESEARCH.**—Of the amounts appropriated under paragraph (1) for a fiscal year, the Director shall obligate not less than 15 percent to carry out health services research relating to alcohol abuse and alcoholism.

ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 464I. [285n-1] (a) **IN GENERAL.**—There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of alcohol abuse and alcoholism. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in alcohol abuse and alcoholism or the prevention of such.

(b) **BIENNIAL REPORT.**—The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

NATIONAL ALCOHOL RESEARCH CENTER

SEC. 464J. [285n-2] (a) The Secretary acting through the Institute may designate National Alcohol Research Centers for the purpose of interdisciplinary research relating to alcoholism and other biomedical, behavioral, and social issues related to alcoholism

¹Now codified to section 3324 of title 31, United States Code.

and alcohol abuse. No entity may be designated as a Center unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reasonably require. The Secretary may not approve such an application unless—

(1) the application contains or is supported by reasonable assurances that—

(A) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on alcoholism and other alcohol problems and to provide coordination of such research among such disciplines;

(B) the applicant has available to it sufficient facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application,

(C) the applicant has facilities and personnel to provide training in the prevention and treatment of alcoholism and other alcohol problems;

(D) the applicant has the capacity to train predoctoral and postdoctoral students for careers in research on alcoholism and other alcohol problems;

(E) the applicant has the capacity to conduct courses on alcohol problems and research on alcohol problems for undergraduate and graduate students, and medical and osteopathic, nursing, social work, and other specialized graduate students; and

(F) the applicant has the capacity to conduct programs of continuing education in such medical, legal, and social service fields as the Secretary may require.

(2) the application contains a detailed five-year plan for research relating to alcoholism and other alcohol problems.

(b) The Secretary shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term "construction" has the meaning given that term by section 701(1).¹ The Secretary shall include in the grants made under this section for fiscal year beginning after September 30, 1981, a grant to a designated Center for research on the effects of alcohol on the elderly.

Subpart 15—National Institute on Drug Abuse

PURPOSE OF INSTITUTE

SEC. 464L. [285o] (a) IN GENERAL.—The general purpose of the National Institute on Drug Abuse (hereafter in this subpart referred to as the "Institute") is the conduct and support of bio-

¹ So in law. See section 2(a) of Public Law 102-352 (106 Stat. 938). Section 701(1) does not provide a definition for the term "construction", but former section 701(1) did provide such a definition. Public Law 102-408 amended title VII generally; definitions for the title are now provided in section 799, and that section does not define the term "construction".

medical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers.

(b) RESEARCH PROGRAM.—The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of drug abuse. In carrying out the program, the Director of the Institute shall give special consideration to projects relating to drug abuse among women (particularly with respect to pregnant women).

(c) COLLABORATION.—The Director of the Institute shall collaborate with the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

(d) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, other than section 464P, there are authorized to be appropriated \$440,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(2) ALLOCATION FOR HEALTH SERVICES RESEARCH.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Director shall obligate not less than 15 percent to carry out health services research relating to drug abuse.

ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 464M. [285o-1] (a) IN GENERAL.—There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of drug abuse. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in drug abuse and the prevention of such abuse.

(b) REPORT.—The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

DRUG ABUSE RESEARCH CENTERS

SEC. 464N. [285o-2] (a) AUTHORITY.—The Director of the Institute may designate National Drug Abuse Research Centers for the purpose of interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse. No entity may be designated as a Center unless an application therefore has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reasonably require. The Secretary may not approve such an application unless—

(1) the application contains or is supported by reasonable assurances that—

(A) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on drug abuse and to

provide coordination of such research among such disciplines;

(B) the applicant has available to it sufficient facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application;

(C) the applicant has facilities and personnel to provide training in the prevention and treatment of drug abuse;

(D) the applicant has the capacity to train predoctoral and postdoctoral students for careers in research on drug abuse;

(E) the applicant has the capacity to conduct courses on drug abuse problems and research on drug abuse for undergraduate and graduate students, and medical and osteopathic, nursing, social work, and other specialized graduate students; and

(F) the applicant has the capacity to conduct programs of continuing education in such medical, legal, and social service fields as the Secretary may require.

(2) the application contains a detailed five-year plan for research relating to drug abuse.

(b) GRANTS.—The Director of the Institute shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term "construction" has the meaning given that term by section 701(1).¹

OFFICE ON AIDS

SEC. 464O. [285o-3] The Director of the Institute shall establish within the Institute an Office on AIDS. The Office shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

(1) primary prevention of the spread of HIV, including transmission via drug abuse;

(2) drug abuse services research; and

(3) other matters determined appropriate by the Director.

MEDICATION DEVELOPMENT PROGRAM

SEC. 464P. [285o-4] (a) ESTABLISHMENT.—There is established in the Institute a Medication Development Program through which the Director of such Institute shall—

(1) conduct periodic meetings with the Commissioner of Food and Drugs to discuss measures that may facilitate the approval process of drug abuse treatments;

(2) encourage and promote (through grants, contracts, international collaboration, or otherwise) expanded research programs, investigations, experiments, community trials, and

¹ See footnote on page 334.

studies, into the development and use of medications to treat drug addiction;

(3) establish or provide for the establishment of research facilities;

(4) report on the activities of other relevant agencies relating to the development and use of pharmacotherapeutic treatments for drug addiction;

(5) collect, analyze, and disseminate data useful in the development and use of pharmacotherapeutic treatments for drug addiction and collect, catalog, analyze, and disseminate through international channels, the results of such research;

(6) directly or through grants, contracts, or cooperative agreements, support training in the fundamental sciences and clinical disciplines related to the pharmacotherapeutic treatment of drug abuse, including the use of training stipends, fellowships, and awards where appropriate; and

(7) coordinate the activities conducted under this section with related activities conducted within the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Mental Health, and other appropriate institutes and shall consult with the Directors of such Institutes.

(b) DUTIES.—In carrying out the activities described in subsection (a), the Director of the Institute—

(1) shall collect and disseminate through publications and other appropriate means, information pertaining to the research and other activities under this section;

(2) shall make grants to or enter into contracts and cooperative agreements with individuals and public and private entities to further the goals of the program;

(3) may, in accordance with section 496, and in consultation with the National Advisory Council on Drug Abuse, acquire, construct, improve, repair, operate, and maintain pharmacotherapeutic research centers, laboratories, and other necessary facilities and equipment, and such other real or personal property as the Director determines necessary, and may, in consultation with such Advisory Council, make grants for the construction or renovation of facilities to carry out the purposes of this section;

(4) may accept voluntary and uncompensated services;

(5) may accept gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible; and

(6) shall take necessary action to ensure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

(c) REPORT.—

(1) IN GENERAL.—Not later than December 31, 1992, and each December 31 thereafter, the Director of the Institute shall submit to the Office of National Drug Control Policy established under section 1002 of the Anti-Drug Abuse Act of 1988 (21 U.S.C. 1501) a report, in accordance with paragraph (3), that describes the objectives and activities of the program assisted under this section.

(2) NATIONAL DRUG CONTROL STRATEGY.—The Director of National Drug Control Policy shall incorporate, by reference or otherwise, each report submitted under this subsection in the National Drug Control Strategy submitted the following February 1 under section 1005 of the Anti-Drug Abuse Act of 1988 (21 U.S.C. 1504).

(d) DEFINITION.—For purposes of this section, the term “pharmacotherapeutics” means medications used to treat the symptoms and disease of drug abuse, including medications to—

- (1) block the effects of abused drugs;
- (2) reduce the craving for abused drugs;
- (3) moderate or eliminate withdrawal symptoms;
- (4) block or reverse the toxic effect of abused drugs; or
- (5) prevent relapse in persons who have been detoxified from drugs of abuse.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$85,000,000 for fiscal year 1993, and \$95,000,000 for fiscal year 1994.

Subpart 16—National Institute of Mental Health

PURPOSE OF INSTITUTE

SEC. 464R. [285p] (a) IN GENERAL.—The general purpose of the National Institute of Mental Health (hereafter in this subpart referred to as the “Institute”) is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the cause, diagnosis, treatment, control and prevention of mental illness.

(b) RESEARCH PROGRAM.—The research program established under this subpart shall include support for biomedical and behavioral neuroscience and shall be designed to further the treatment and prevention of mental illness, the promotion of mental health, and the study of the psychological, social and legal factors that influence behavior.

(c) COLLABORATION.—The Director of the Institute shall collaborate with the Administrator of the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

(d) INFORMATION WITH RESPECT TO SUICIDE.—

(1) IN GENERAL.—The Director of the Institute shall—

(A) develop and publish information with respect to the causes of suicide and the means of preventing suicide; and

(B) make such information generally available to the public and to health professionals.

(2) YOUTH SUICIDE.—Information described in paragraph (1) shall especially relate to suicide among individuals under 24 years of age.

(e) ASSOCIATE DIRECTOR FOR SPECIAL POPULATIONS.—

(1) IN GENERAL.—The Director of the Institute shall designate an Associate Director for Special Populations.

(2) DUTIES.—The Associate Director for Special Populations shall—

(A) develop and coordinate research policies and programs to assure increased emphasis on the mental health needs of women and minority populations;

(B) support programs of basic and applied social and behavioral research on the mental health problems of women and minority populations;

(C) study the effects of discrimination on institutions and individuals, including majority institutions and individuals;

(D) support and develop research designed to eliminate institutional discrimination; and

(E) provide increased emphasis on the concerns of women and minority populations in training programs, service delivery programs, and research endeavors of the Institute.

(f) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated \$675,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(2) ALLOCATION FOR HEALTH SERVICES RESEARCH.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Director shall obligate not less than 15 percent to carry out health services research relating to mental health.

ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 464S. [285p-1] (a) IN GENERAL.—There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of mental disorder. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in mental disorder and the prevention of such.

(b) REPORT.—The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

OFFICE OF RURAL MENTAL HEALTH RESEARCH

SEC. 464T. [285p-2] (a) IN GENERAL.—There is established within the Institute an office to be known as the Office of Rural Mental Health Research (hereafter in this section referred to as the "Office"). The Office shall be headed by a director, who shall be appointed by the Director of such Institute from among individuals experienced or knowledgeable in the provision of mental health services in rural areas. The Secretary shall carry out the authorities established in this section acting through the Director of the Office.

(b) COORDINATION OF ACTIVITIES.—The Director of the Office, in consultation with the Director of the Institute and with the Director of the Office of Rural Health Policy, shall—

(1) coordinate the research activities of the Department of Health and Human Services as such activities relate to the mental health of residents of rural areas; and

(2) coordinate the activities of the Office with similar activities of public and nonprofit private entities.

(c) RESEARCH, DEMONSTRATIONS, EVALUATIONS, AND DISSEMINATION.—The Director of the Office may, with respect to the mental health of adults and children residing in rural areas—

(1) conduct research on conditions that are unique to the residents of rural areas, or more serious or prevalent in such residents;

(2) conduct research on improving the delivery of services in such areas; and

(3) disseminate information to appropriate public and nonprofit private entities.

(d) AUTHORITY REGARDING GRANTS AND CONTRACTS.—The Director of the Office may carry out the authorities established in subsection (c) directly and through grants, cooperative agreements, or contracts with public or nonprofit private entities.

(e) REPORT TO CONGRESS.—Not later than February 1, 1993, and each fiscal year thereafter, the Director shall submit to the Subcommittee on Health and the Environment of the Committee on Energy and Commerce (of the House of Representatives), and to the Committee on Labor and Human Resources (of the Senate), a report describing the activities of the Office during the preceding fiscal year, including a summary of the activities of demonstration projects and a summary of evaluations of the projects.

OFFICE ON AIDS

SEC. 464U. [285p-3] The Director of the Institute shall establish within the Institute an Office on AIDS. The Office shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

(1) primary prevention of the spread of HIV, including transmission via sexual behavior;

(2) mental health services research; and

(3) other matters determined appropriate by the Director.

Subpart 17—National Institute of Nursing Research

PURPOSE OF THE INSTITUTE

SEC. 464V. [285q] The general purpose of the National Institute of Nursing Research (in this subpart referred to as the “Institute”) is the conduct and support of, and dissemination of information respecting, basic and clinical nursing research, training, and other programs in patient care research.

SPECIFIC AUTHORITIES

SEC. 464W. [285q-1] To carry out section 464V, the Director of the Institute may provide research training and instruction and

establish, in the Institute and other nonprofit institutions, research traineeships and fellowships in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with and the families of individuals with acute and chronic illnesses. The Director of the Institute may provide individuals receiving such training and instruction or such traineeships or fellowships with such stipends and allowances (including amounts for travel and subsistence and dependency allowances) as the Director determines necessary. The Director may make grants to nonprofit institutions to provide such training and instruction and traineeships and fellowships.

ADVISORY COUNCIL

SEC. 464X. [285q-2] (a)(1) The Secretary shall appoint an advisory council for the Institute which shall advise, assist, consult with, and make recommendations to the Secretary and the Director of the Institute on matters related to the activities carried out by and through the Institute and the policies respecting such activities.

(2) The advisory council for the Institute may recommend to the Secretary acceptance, in accordance with section 2701,¹ of conditional gifts for study, investigations, and research and for the acquisition of grounds or construction, equipping, or maintenance of facilities for the Institute.

(3) The advisory council for the Institute—

(A)(i) may make recommendations to the Director of the Institute respecting research conducted at the Institute,

(ii) may review applications for grants and cooperative agreements for research or training and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the Institute is concerned and with the approval of the Director of the Institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b)(1) The advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary.

(2) The ex officio members of the advisory council shall consist of—

¹ Probably should be section 231. That section formerly was section 2701, and was redesignated by subsection (a)(2) of section 2010 of Public Law 103-43 (107 Stat. 213). Subsection (b)(5) of such section purported to conform the above reference, but the amendment cannot be executed because the amendment applied to the incorrect section. (The conforming amendment applied to section 485. Section 464X formerly was section 485, and was redesignated by section 1511(b)(2)(B) of Public Law 103-43 (107 Stat. 179).)

(A) the Secretary, the Director of NIH, the Director of the Institute, the chief nursing officer of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs, the Director of the Division of Nursing of the Health Resources and Services Administration (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of the advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including public health and the behavioral or social sciences) relevant to the activities of the Institute. Of the members appointed pursuant to this subparagraph, at least seven shall be professional nurses who are recognized experts in the area of clinical practice, education, or research.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of the advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of the advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule.

(c) The term of office of an appointed member of the advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) The chairman of the advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the Institute to be the chairman of the advisory council. The term of office of the chairman shall be two years.

(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the Institute, but at least three times each fiscal year. The location of the meetings of the advisory council is subject to the approval of the Director of the Institute.

(f) The Director of the Institute shall designate a member of the staff of the Institute to serve as the executive secretary of the advisory council. The Director of the Institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of the Institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

(g) The advisory council may prepare, for inclusion in the biennial report made under section 464Y, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the Institute in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Institute. The advisory council may prepare such additional reports as it may determine appropriate.

BIENNIAL REPORT

SEC. 464Y. [285q-3] The Director of the Institute after consultation with the advisory council for the Institute, shall prepare for inclusion in the biennial report made under section 403 a biennial report which shall consist of a description of the activities of the Institute and program policies of the Director of the Institute in the fiscal years respecting which the report is prepared. The Director of the Institute may prepare such additional reports as the Director determines appropriate. The Director of the Institute shall provide the advisory council of the Institute an opportunity for the submission of the written comments referred to in section 464X(g).

PART D—NATIONAL LIBRARY OF MEDICINE

Subpart 1—General Provisions

PURPOSE, ESTABLISHMENT, AND FUNCTIONS OF THE NATIONAL LIBRARY OF MEDICINE

SEC. 465. [286] (a) In order to assist the advancement of medical and related sciences and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health, there is established the National Library of Medicine (hereafter in this part referred to as the "Library").

(b) The Secretary, through the Library and subject to subsection (d), shall—

(1) acquire and preserve books, periodicals, prints, films, recordings, and other library materials pertinent to medicine;

(2) organize the materials specified in paragraph (1) by appropriate cataloging, indexing, and bibliographical listings;

(3) publish and disseminate the catalogs, indexes, and bibliographies referred to in paragraph (2);

(4) make available, through loans, photographic or other copying procedures, or otherwise, such materials in the Library as the Secretary determines appropriate;

(5) provide reference and research assistance;

(6) publicize the availability from the Library of the products and services described in any of paragraphs (1) through (5);

(7) promote the use of computers and telecommunications by health professionals (including health professionals in rural areas) for the purpose of improving access to biomedical information for health care delivery and medical research; and

(8) engage in such other activities as the Secretary determines appropriate and as the Library's resources permit.

(c) The Secretary may exchange, destroy, or otherwise dispose of any books, periodicals, films, and other library materials not needed for the permanent use of the Library.

(d)(1) The Secretary may, after obtaining the advice and recommendations of the Board of Regents, prescribe rules under which the Library will—

(A) provide copies of its publications or materials,

(B) will make available its facilities for research, or

(C) will make available its bibliographic, reference, or other services,

to public and private entities and individuals.

(2) Rules prescribed under paragraph (1) may provide for making available such publications, materials, facilities, or services—

(A) without charge as a public service,

(B) upon a loan, exchange, or charge basis, or

(C) in appropriate circumstances, under contract arrangements made with a public or other nonprofit entity.

(e) Whenever the Secretary, with the advice of the Board of Regents, determines that—

(1) in any geographic area of the United States there is no regional medical library adequate to serve such area;

(2) under criteria prescribed for the administration of section 475, there is a need for a regional medical library to serve such area; and

(3) because there is no medical library located in such area which, with financial assistance under section 475, can feasibly be developed into a regional medical library adequate to serve such area,

the Secretary may establish, as a branch of the Library, a regional medical library to serve the needs of such area.

(f) Section 231 shall be applicable to the acceptance and administration of gifts made for the benefit of the Library or for carrying out any of its functions, and the Board of Regents shall make recommendations to the Secretary relating to establishment within the Library of suitable memorials to the donors.

(g) For purposes of this part, the terms "medicine" and "medical", except when used in section 466, include preventive and therapeutic medicine, dentistry, pharmacy, hospitalization, nursing, public health, and the fundamental sciences related thereto, and other related fields of study, research, or activity.

BOARD OF REGENTS

SEC. 466. [286a] (a)(1)(A) The Board of Regents of the National Library of Medicine consists of ex officio members and ten members appointed by the Secretary.

(B) The ex officio members are the Surgeons General of the Public Health Service, the Army, the Navy, and the Air Force, the Chief Medical Director of the Department of Veterans Affairs, the Dean of the Uniformed Services University of the Health Sciences, the Assistant Director for Biological, Behavioral, and Social Sciences of the National Science Foundation, the Director of the National Agricultural Library, and the Librarian of Congress (or their designees).

(C) The appointed members shall be selected from among leaders in the various fields of the fundamental sciences, medicine, dentistry, public health, hospital administration, pharmacology, health communications technology, or scientific or medical library work, or in public affairs. At least six of the appointed members shall be selected from among leaders in the fields of medical, dental, or public health research or education.

(2) The Board shall annually elect one of the appointed members to serve as chairman until the next election. The Secretary shall designate a member of the Library staff to act as executive secretary of the Board.

(b) The Board shall advise, consult with, and make recommendations to the Secretary on matters of policy in regard to the Library, including such matters as the acquisition of materials for the Library, the scope, content, and organization of the Library's services, and the rules under which its materials, publications, facilities, and services shall be made available to various kinds of users. The Secretary shall include in the annual report of the Secretary to the Congress a statement covering the recommendations made by the Board and the disposition thereof. The Secretary may use the services of any member of the Board in connection with matters related to the work of the Library, for such periods, in addition to conference periods, as the Secretary may determine.

(c) Each appointed member of the Board shall hold office for a term of four years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the predecessor of such member was appointed shall be appointed for the remainder of such term. None of the appointed members shall be eligible for reappointment within one year after the end of the preceding term of such member.

LIBRARY FACILITIES

SEC. 467. [286a-1] There are authorized to be appropriated amounts sufficient for the erection and equipment of suitable and adequate buildings and facilities for use of the Library. The Administrator of General Services may acquire, by purchase, condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for such buildings and facilities and to erect thereon, furnish, and equip such buildings and facilities. The amounts authorized to be appropriated by this section include the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.

AUTHORIZATION OF APPROPRIATIONS

SEC. 468. [286a-2] (a) For the purpose of carrying out this part, there are authorized to be appropriated \$150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

(b) Amounts appropriated under subsection (a) and made available for grants or contracts under any of sections 472 through 476 shall remain available until the end of the fiscal year following the fiscal year for which the amounts were appropriated.

Subpart 2—Financial Assistance

DEFINITIONS

SEC. 470. [286b-1] As used in this subpart—

(1) the term “medical library” means a library related to the sciences related to health; and

(2) the term “sciences related to health” includes medicine, osteopathy, dentistry, and public health, and fundamental and applied sciences when related thereto.

NATIONAL MEDICAL LIBRARIES ASSISTANCE ADVISORY BOARD

SEC. 471. [286b-2] (a) The Board of Regents of the National Library of Medicine shall also serve as the National Medical Libraries Assistance Advisory Board (hereafter in this subpart referred to as the “Board”).

(b) The Board shall advise and assist the Secretary in the preparation of general regulations and with respect to policy matters arising in the administration of this subpart.

(c) The Secretary may use the services of any member of the Board, in connection with matters related to the administration of this part for such periods, in addition to conference periods, as the Secretary may determine.

(d) Appointed members of the Board who are not otherwise in the employ of the United States, while attending conferences of the Board or otherwise serving at the request of the Secretary in connection with the administration of this subpart, shall be entitled to receive compensation, per diem in lieu of subsistence, and travel expenses in the same manner and under the same conditions as that prescribed under section 208(c) when attending conferences, traveling, or serving at the request of the Secretary in connection with the Board's function under this section.

GRANTS FOR TRAINING IN MEDICAL LIBRARY SCIENCES

SEC. 472. [286b-3] The Secretary shall make grants—

(1) to individuals to enable them to accept traineeships and fellowships leading to postbaccalaureate academic degrees in the field of medical library science, in related fields pertaining to sciences related to health, or in the field of the communication of information;

(2) to individuals who are librarians or specialists in information on sciences relating to health, to enable them to undergo intensive training or retraining so as to attain greater com-

petence in their occupations (including competence in the fields of automatic data processing and retrieval);

(3) to assist appropriate public and private nonprofit institutions in developing, expanding, and improving training programs in library science and the field of communications of information pertaining to sciences relating to health; and

(4) to assist in the establishment of internship programs in established medical libraries meeting standards which the Secretary shall prescribe.

ASSISTANCE FOR SPECIAL SCIENTIFIC PROJECTS, AND FOR RESEARCH AND DEVELOPMENT IN MEDICAL LIBRARY SCIENCE AND RELATED FIELDS

SEC. 473. [286b-4] (a) The Secretary shall make grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists for the compilation of existing, or the writing of original, contributions relating to scientific, social, or cultural advancements in sciences related to health. In making such grants, the Secretary shall make appropriate arrangements under which the facilities of the Library and the facilities of libraries of public and private nonprofit institutions of higher learning may be made available in connection with the projects for which such grants are made.

(b) The Secretary shall make grants to appropriate public or private nonprofit institutions and enter into contracts with appropriate persons, for purposes of carrying out projects of research, investigations, and demonstrations in the field of medical library science and related activities and for the development of new techniques, systems, and equipment, for processing, storing, retrieving, and distributing information pertaining to sciences related to health.

(c)(1) The Secretary shall make grants to public or nonprofit private institutions for the purpose of carrying out projects of research on, and development and demonstration of, new education technologies.

(2) The purposes for which a grant under paragraph (1) may be made include projects concerning—

(A) computer-assisted teaching and testing of clinical competence at health professions and research institutions;

(B) the effective transfer of new information from research laboratories to appropriate clinical applications;

(C) the expansion of the laboratory and clinical uses of computer-stored research databases; and

(D) the testing of new technologies for training health care professionals.

(3) The Secretary may not make a grant under paragraph (1) unless the applicant for the grant agrees to make the projects available with respect to—

(A) assisting in the training of health professions students; and

(B) enhancing and improving the capabilities of health professionals regarding research and teaching.

GRANTS FOR ESTABLISHING, EXPANDING, AND IMPROVING THE BASIC RESOURCES OF MEDICAL LIBRARIES AND RELATED INSTRUMENTALITIES

SEC. 474. [286b-5] (a) The Secretary shall make grants of money, materials, or both, to public or private nonprofit medical libraries and related scientific communication instrumentalities for the purpose of establishing, expanding, and improving their basic medical library or related resources. A grant under this subsection may be used for—

(1) the acquisition of books, journals, photographs, motion picture and other films, and other similar materials;

(2) cataloging, binding, and other services and procedures for processing library resource materials for use by those who are served by the library or related instrumentality;

(3) the acquisition of duplication devices, facsimile equipment, film projectors, recording equipment, and other equipment to facilitate the use of the resources of the library or related instrumentality by those who are served by it; and

(4) the introduction of new technologies in medical librarianship.

(b)(1) The amount of any grant under this section to any medical library or related instrumentality shall be determined by the Secretary on the basis of the scope of library or related services provided by such library or instrumentality in relation to the population and purposes served by it. In making a determination of the scope of services served by any medical library or related instrumentality, the Secretary shall take into account—

(A) the number of graduate and undergraduate students making use of the resources of such library or instrumentality;

(B) the number of physicians and other practitioners in the sciences related to health utilizing the resources of such library or instrumentality;

(C) the type of supportive staffs, if any, available to such library or instrumentality;

(D) the type, size, and qualifications of the faculty of any school with which such library or instrumentality is affiliated;

(E) the staff of any hospital or hospitals or of any clinic or clinics with which such library or instrumentality is affiliated; and

(F) the geographic area served by such library or instrumentality and the availability within such area of medical library or related services provided by other libraries or related instrumentalities.

(2) Grants to such medical libraries or related instrumentalities under this section shall be in such amounts as the Secretary may by regulation prescribe with a view to assuring adequate continuing financial support for such libraries or instrumentalities from other sources during and after the period for which grants are provided, except that in no case shall any grant under this section to a medical library or related instrumentality for any fiscal year exceed \$1,000,000.

GRANTS AND CONTRACTS FOR ESTABLISHMENT OF REGIONAL MEDICAL LIBRARIES

SEC. 475. [286b-6] (a) The Secretary, with the advice of the Board, shall make grants to and enter into contracts with existing public or private nonprofit medical libraries so as to enable each of them to serve as the regional medical library for the geographical area in which it is located.

(b) The uses for which grants and contracts under this section may be employed include the—

(1) acquisition of books, journals, and other similar materials;

(2) cataloging, binding, and other procedures for processing library resource materials for use by those who are served by the library;

(3) acquisition of duplicating devices and other equipment to facilitate the use of the resources of the library by those who are served by it;

(4) acquisition of mechanisms and employment of personnel for the speedy transmission of materials from the regional library to local libraries in the geographic area served by the regional library; and

(5) planning for services and activities under this section.

(c)(1) Grants and contracts under this section shall only be made to or entered into with medical libraries which agree—

(A) to modify and increase their library resources, and to supplement the resources of cooperating libraries in the region, so as to be able to provide adequate supportive services to all libraries in the region as well as to individual users of library services; and

(B) to provide free loan services to qualified users and make available photoduplicated or facsimile copies of biomedical materials which qualified requesters may retain.

(2) The Secretary, in awarding grants and contracts under this section, shall give priority to medical libraries having the greatest potential of fulfilling the needs for regional medical libraries. In determining the priority to be assigned to any medical library, the Secretary shall consider—

(A) the adequacy of the library (in terms of collections, personnel, equipment, and other facilities) as a basis for a regional medical library; and

(B) the size and nature of the population to be served in the region in which the library is located.

(d) Grants and contracts under this section for basic resource materials to a library may not exceed—

(1) 50 percent of the library's annual operating expense (exclusive of Federal financial assistance under this part) for the preceding year; or

(2) in case of the first year in which the library receives a grant under this section for basic resource materials, 50 percent of its average annual operating expenses over the past three years (or if it had been in operation for less than three years, its annual operating expenses determined by the Secretary in accordance with regulations).

FINANCIAL SUPPORT OF BIOMEDICAL SCIENTIFIC PUBLICATIONS

SEC. 476. [286b-7] (a) The Secretary, with the advice of the Board, shall make grants to, and enter into appropriate contracts with, public or private nonprofit institutions of higher education and individual scientists for the purpose of supporting biomedical scientific publications of a nonprofit nature and to procure the compilation, writing, editing, and publication of reviews, abstracts, indices, handbooks, bibliographies, and related matter pertaining to scientific works and scientific developments.

(b) Grants under subsection (a) in support of any single periodical publication may not be made for more than three years, except in those cases in which the Secretary determines that further support is necessary to carry out the purposes of subsection (a).

GRANT PAYMENTS, RECORDS, AND AUDIT

SEC. 477. [286b-8] (a) Payments under grants made under sections 472, 473, 474, 475, and 476 may be made in advance or by way of reimbursement and in such installments as the Secretary shall prescribe by regulation after consultation with the Board.

(b)(1) Each recipient of a grant under this subpart shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to any grant received under this subpart.

Subpart 3—National Center for Biotechnology Information

PURPOSE, ESTABLISHMENT, FUNCTIONS, AND FUNDING OF THE
NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

SEC. 478. [286c] (a) In order to focus and expand the collection, storage, retrieval, and dissemination of the results of biotechnology research by information systems, and to support and enhance the development of new information technologies to aid in the understanding of the molecular processes that control health and disease, there is established the National Center for Biotechnology Information (hereinafter in this section referred to as the "Center") in the National Library of Medicine.

(b) The Secretary, through the Center and subject to section 465(d), shall—

(1) design, develop, implement, and manage automated systems for the collection, storage, retrieval, analysis, and dissemination of knowledge concerning human molecular biology, biochemistry, and genetics;

(2) perform research into advanced methods of computer-based information processing capable of representing and ana-

lyzing the vast number of biologically important molecules and compounds;

(3) enable persons engaged in biotechnology research and medical care to use systems developed under paragraph (1) and methods described in paragraph (2); and

(4) coordinate, as much as is practicable, efforts to gather biotechnology information on an international basis.

Subpart 4—National Information Center on Health Services Research and Health Care Technology

NATIONAL INFORMATION CENTER

SEC. 478A. [286d] (a) There is established within the Library an entity to be known as the National Information Center on Health Services Research and Health Care Technology (in this section referred to as the "Center").

(b) The purpose of the Center is the collection, storage, analysis, retrieval, and dissemination of information on health services research, clinical practice guidelines, and on health care technology, including the assessment of such technology. Such purpose includes developing and maintaining data bases and developing and implementing methods of carrying out such purpose.

(c) The Director of the Center shall ensure that information under subsection (b) concerning clinical practice guidelines is collected and maintained electronically and in a convenient format. Such Director shall develop and publish criteria for the inclusion of practice guidelines and technology assessments in the information center database.

(d) The Secretary, acting through the Center, shall coordinate the activities carried out under this section through the Center with related activities of the Administrator for Health Care Policy and Research.

PART E—OTHER AGENCIES OF NIH

Subpart 1—National Center for Research Resources

GENERAL PURPOSE

SEC. 479. [287] The general purpose of the National Center for Research Resources (in this subpart referred to as the "Center") is to strengthen and enhance the research environments of entities engaged in health-related research by developing and supporting essential research resources.

ADVISORY COUNCIL

SEC. 480. [287a] (a)(1) The Secretary shall appoint an advisory council for the Center which shall advise, assist, consult with, and make recommendations to the Secretary and the Director of the Center on matters related to the activities carried out by and through the Center and the policies respecting such activities.

(2) The advisory council for the Center may recommend to the Secretary acceptance, in accordance with section 231, of conditional gifts for study, investigations, and research and for the acquisition

of grounds or construction, equipping, or maintenance of facilities for the Center.

(3) The advisory council for the Center—

(A)(i) may make recommendations to the Director of the Center respecting research conducted at the Center,

(ii) may review applications for grants and cooperative agreements for research or training and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Center;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the Center is concerned and with the approval of the Director of the Center make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b)(1) The advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary.

(2) The ex officio members of the advisory council shall consist of—

(A) the Secretary, the Director of NIH, the Director of the Center, the Chief Medical Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of the advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including public health and the behavioral or social sciences) relevant to the activities of the Center.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of the advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of the advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule.

(c) The term of office of an appointed member of the advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remain-

der of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) The chairman of the advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the Center to be the chairman of the advisory council. The term of office of the chairman shall be two years.

(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the Center, but at least three times each fiscal year. The location of the meetings of the advisory council is subject to the approval of the Director of the Center.

(f) The Director of the Center shall designate a member of the staff of the Center to serve as the executive secretary of the advisory council. The Director of the Center shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of the Center shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

(g) The advisory council may prepare, for inclusion in the biennial report made under section 481, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the Center in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Center. The advisory council may prepare such additional reports as it may determine appropriate.

(h) This section does not terminate the membership of the advisory council for the Center which was in existence on the date of enactment of the Health Research Extension Act of 1985. After such date—

(1) the Secretary shall make appointments to such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

(2) the advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

(3) the Director of the Center shall perform for such advisory council the functions prescribed by this section.

BIENNIAL REPORT

SEC. 481. [287a-1] The Director of the Center, after consultation with the advisory council for the Center, shall prepare for inclusion in the biennial report made under section 403 a biennial re-

port which shall consist of a description of the activities of the Center and program policies of the Director of the Center in the fiscal years respecting which the report is prepared. The Director of the Center may prepare such additional reports as the Director determines appropriate. The Director of the Center shall provide the advisory council of the Center an opportunity for the submission of the written comments referred to in section 480(g).

BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES

SEC. 481A. [287a-2] (a) MODERNIZATION AND CONSTRUCTION OF FACILITIES.—

(1) IN GENERAL.—The Director of NIH, acting through the Director of the Center, may make grants to public and non-profit private entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities, subject to the provisions of this section.

(2) CONSTRUCTION AND COST OF CONSTRUCTION.—For purposes of this section, the terms “construction” and “cost of construction” include the construction of new buildings and the expansion, renovation, remodeling, and alteration of existing buildings, including architects’ fees, but do not include the cost of acquisition of land or off-site improvements.

(b) SCIENTIFIC AND TECHNICAL REVIEW BOARDS FOR MERIT-BASED REVIEW OF PROPOSALS.—

(1) IN GENERAL; APPROVAL AS PRECONDITION TO GRANTS.—

(A) There is established within the Center a Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities (referred to in this section as the “Board”).

(B) The Director of the Center may approve an application for a grant under subsection (a) only if the Board has under paragraph (2) recommended the application for approval.

(2) DUTIES.—

(A) The Board shall provide advice to the Director of the Center and the advisory council established under section 480 (in this section referred to as the “Advisory Council”) on carrying out this section.

(B) In carrying out subparagraph (A), the Board shall make a determination of the merit of each application submitted for a grant under subsection (a), after consideration of the requirements established in subsection (c), and shall report the results of the determination to the Director of the Center and the Advisory Council. Such determinations shall be conducted in a manner consistent with procedures established under section 492.

(C) In carrying out subparagraph (A), the Board shall, in the case of applications recommended for approval, make recommendations to the Director and the Advisory Council on the amount that should be provided in the grant.

(D) In carrying out subparagraph (A), the Board shall prepare an annual report for the Director of the Center and the Advisory Council describing the activities of the

Board in the fiscal year for which the report is made. Each such report shall be available to the public, and shall—

(i) summarize and analyze expenditures made under this section;

(ii) provide a summary of the types, numbers, and amounts of applications that were recommended for grants under subsection (a) but that were not approved by the Director of the Center; and

(iii) contain the recommendations of the Board for any changes in the administration of this section.

(3) MEMBERSHIP.—

(A) Subject to subparagraph (B), the Board shall be composed of 9 appointed members, and such ex officio members as the Director of the Center determines to be appropriate.

(B) Not more than 3 individuals who are officers or employees of the Federal Government may serve as members of the Board.

(4) CERTAIN REQUIREMENTS REGARDING MEMBERSHIP.—In selecting individuals for membership on the Board, the Director of the Center shall ensure that the members are individuals who, by virtue of their training or experience, are eminently qualified to perform peer review functions. In selecting such individuals for such membership, the Director of the Center shall ensure that the members of the Board collectively—

(A) are experienced in the planning, construction, financing, and administration of entities that conduct biomedical or behavioral research sciences;

(B) are knowledgeable in making determinations of the need of entities for biomedical or behavioral research facilities, including such facilities for the dentistry, nursing, pharmacy, and allied health professions;

(C) are knowledgeable in evaluating the relative priorities for applications for grants under subsection (a) in view of the overall research needs of the United States; and

(D) are experienced with emerging centers of excellence, as described in subsection (c)(3).

(5) CERTAIN AUTHORITIES.—

(A) In carrying out paragraph (2), the Board may convene workshops and conferences, and collect data as the Board considers appropriate.

(B) In carrying out paragraph (2), the Board may establish subcommittees within the Board. Such subcommittees may hold meetings as determined necessary to enable the subcommittee to carry out its duties.

(6) TERMS.—

(A) Except as provided in subparagraph (B), each appointed member of the Board shall hold office for a term of 4 years. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of the term of the predecessor.

(B) Of the initial members appointed to the Board (as specified by the Director of the Center when making the appointments)—

- (i) 3 shall hold office for a term of 3 years;
- (ii) 3 shall hold office for a term of 2 years; and
- (iii) 3 shall hold office for a term of 1 year.

(C) No member is eligible for reappointment to the Board until 1 year has elapsed after the end of the most recent term of the member.

(7) COMPENSATION.—Members of the Board who are not officers or employees of the United States shall receive for each day the members are engaged in the performance of the functions of the Board compensation at the same rate received by members of other national advisory councils established under this title.

(c) REQUIREMENTS FOR GRANTS.—

(1) IN GENERAL.—The Director of the Center may make a grant under subsection (a) only if the applicant for the grant meets the following conditions:

(A) The applicant is determined by such Director to be competent to engage in the type of research for which the proposed facility is to be constructed.

(B) The applicant provides assurances satisfactory to the Director that—

(i) for not less than 20 years after completion of the construction, the facility will be used for the purposes of research for which it is to be constructed;

(ii) sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility;

(iii) sufficient funds will be available, when construction is completed, for the effective use of the facility for the research for which it is being constructed; and

(iv) the proposed construction will expand the applicant's capacity for research, or is necessary to improve or maintain the quality of the applicant's research.

(C) The applicant meets reasonable qualifications established by the Director with respect to—

(i) the relative scientific and technical merit of the applications, and the relative effectiveness of the proposed facilities, in expanding the capacity for biomedical or behavioral research and in improving the quality of such research;

(ii) the quality of the research or training, or both, to be carried out in the facilities involved;

(iii) the need of the applicant for such facilities in order to maintain or expand the applicant's research and training mission;

(iv) the congruence of the research activities to be carried out within the facility with the research and investigator manpower needs of the United States; and

(v) the age and condition of existing research facilities and equipment.

(D) The applicant has demonstrated a commitment to enhancing and expanding the research productivity of the applicant.

(2) CONSIDERATION OF CERTAIN FACTORS.—In making grants under subsection (a), the Director of the Center may, in addition to the requirements established in paragraph (1), consider the following factors:

(A) To what extent the applicant has the capacity to broaden the scope of research and research training programs of the applicant by promoting—

(i) interdisciplinary research;

(ii) research on emerging technologies, including those involving novel analytical techniques or computational methods; or

(iii) other novel research mechanisms or programs.

(B) To what extent the applicant has broadened the scope of research and research training programs of qualified institutions by promoting genomic research with an emphasis on interdisciplinary research, including research related to pediatric investigations.

(3) INSTITUTIONS OF EMERGING EXCELLENCE.—Of the amounts appropriated under subsection (h) for a fiscal year, the Director of the Center shall make available 25 percent for grants under subsection (a) to applicants that, in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:

(A) The applicant has a plan for research or training advancement and possesses the ability to carry out the plan.

(B) The applicant carries out research and research training programs that have a special relevance to a problem, concern, or unmet health need of the United States.

(C) The applicant has been productive in research or research development and training.

(D) The applicant—

(i) has been designated as a center of excellence under section 739;

(ii) is located in a geographic area whose population includes a significant number of individuals with a health-status deficit, and the applicant provides health services to such individuals; or

(iii) is located in a geographic area in which a deficit in health care technology, services, or research resources may adversely affect health status of the population of the area in the future, and the applicant is carrying out activities with respect to protecting the health status of such population.

(d) REQUIREMENT OF APPLICATION.—The Director of the Center may make a grant under subsection (a) only if an application for the grant is submitted to the Director and the application is in

such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

(e) AMOUNT OF GRANT; PAYMENTS.—

(1) AMOUNT.—The amount of any grant awarded under subsection (a) shall be determined by the Director of the Center, except that such amount shall not exceed—

(A) 50 percent of the necessary cost of the construction of a proposed facility as determined by the Director; or

(B) in the case of a multipurpose facility, 40 percent of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

(2) RESERVATION OF AMOUNTS.—On approval of any application for a grant under subsection (a), the Director of the Center shall reserve, from any appropriation available therefore, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with the construction progress, as the Director may determine appropriate. The reservation of the Director of any amount by the Director under this paragraph may be amended by the Director, either on the approval of an amendment of the application or on the revision of the estimated cost of construction of the facility.

(3) EXCLUSION OF CERTAIN COSTS.—In determining the amount of any grant under this subsection (a), there shall be excluded from the cost of construction an amount equal to the sum of—

(A) the amount of any other Federal grant that the applicant has obtained, or is assured of obtaining, with respect to construction that is to be financed in part by a grant authorized under this section; and

(B) the amount of any non-Federal funds required to be expended as a condition of such other Federal grant.

(4) WAIVER OF LIMITATIONS.—The limitations imposed by paragraph (1) may be waived at the discretion of the Director for applicants meeting the conditions described in paragraphs (1) and (2) of subsection (c).

(f) RECAPTURE OF PAYMENTS.—If, not later than 20 years after the completion of construction for which a grant has been awarded under subsection (a)—

(1) the applicant or other owner of the facility shall cease to be a public or nonprofit private entity; or

(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so);

the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the

amount of the Federal participation bore to the cost of the construction of such facility.

(g) GUIDELINES.—Not later than 6 months after the date of the enactment of this section, the Director of the Center, after consultation with the Advisory Council, shall issue guidelines with respect to grants under subsection (a).

(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

CONSTRUCTION OF REGIONAL CENTERS FOR RESEARCH ON PRIMATES

SEC. 481B. [287a-3] (a) With respect to activities carried out by the National Center for Research Resources to support regional centers for research on primates, the Director of NIH shall, for each of the fiscal years 1994 through 1996, reserve from the amounts appropriated under section 481A(h) \$5,000,000 for the purpose of making awards of grants and contracts to public or non-profit private entities to construct, renovate, or otherwise improve such regional centers. The reservation of such amounts for any fiscal year is subject to the availability of qualified applicants for such awards.

(b) The Director of NIH may not make a grant or enter into a contract under subsection (a) unless the applicant for such assistance agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such subsection, to make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount equal to not less than \$1 for each \$4 of Federal funds provided in such assistance.

Subpart 2—John E. Fogarty International Center for Advanced Study in the Health Sciences

GENERAL PURPOSE

SEC. 482. [287b] The general purpose of the John E. Fogarty International Center for Advanced Study in the Health Sciences is to—

(1) facilitate the assembly of scientists and others in the biomedical, behavioral, and related fields for discussion, study, and research relating to the development of health science internationally;

(2) provide research programs, conferences, and seminars to further international cooperation and collaboration in the life sciences;

(3) provide postdoctorate fellowships for research training in the United States and abroad and promote exchanges of senior scientists between the United States and other countries;

(4) coordinate the activities of the National Institutes of Health concerned with the health sciences internationally; and

(5) receive foreign visitors to the National Institutes of Health.

Subpart 3—National Center for Human Genome Research

PURPOSE OF THE CENTER

SEC. 485B. [287c] (a) The general purpose of the National Center for Human Genome Research (in this subpart referred to as the "Center") is to characterize the structure and function of the human genome, including the mapping and sequencing of individual genes. Such purpose includes—

(1) planning and coordinating the research goal of the genome project;

(2) reviewing and funding research proposals;

(3) developing training programs;

(4) coordinating international genome research;

(5) communicating advances in genome science to the public; and

(6) reviewing and funding proposals to address the ethical and legal issues associated with the genome project (including legal issues regarding patents).

(b) The Director of the Center may conduct and support research training—

(1) for which fellowship support is not provided under section 487; and

(2) that is not residency training of physicians or other health professionals.

(c)(1) Except as provided in paragraph (2), of the amounts appropriated to carry out subsection (a) for a fiscal year, the Director of the Center shall make available not less than 5 percent for carrying out paragraph (6) of such subsection.

(2) With respect to providing funds under subsection (a)(6) for proposals to address the ethical issues associated with the genome project, paragraph (1) shall not apply for a fiscal year if the Director of the Center certifies to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, that the Director has determined that an insufficient number of such proposals meet the applicable requirements of sections 491 and 492.

Subpart 4—Office of Dietary Supplements

SEC. 485C. [287c-11] DIETARY SUPPLEMENTS.

(a) ESTABLISHMENT.—The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.

(b) PURPOSE.—The purposes of the Office are—

(1) to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and

(2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

(c) DUTIES.—The Director of the Office of Dietary Supplements shall—

(1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can

limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;

(2) collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine;

(3) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including—

(A) dietary intake regulations;

(B) the safety of dietary supplements;

(C) claims characterizing the relationship between—

(i) dietary supplements; and

(ii)(I) prevention of disease or other health-related conditions; and

(II) maintenance of health; and

(D) scientific issues arising in connection with the labeling and composition of dietary supplements;

(4) compile a database of scientific research on dietary supplements and individual nutrients; and

(5) coordinate funding relating to dietary supplements for the National Institutes of Health.

(d) DEFINITION.—As used in this section, the term “dietary supplement” has the meaning given the term in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section \$5,000,000 for fiscal year 1994 and such sums as may be necessary for each subsequent fiscal year.

PART F—RESEARCH ON WOMEN'S HEALTH

SEC. 486. [287d] OFFICE OF RESEARCH ON WOMEN'S HEALTH.

(a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Research on Women's Health (in this part referred to as the “Office”). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

(b) PURPOSE.—The Director of the Office shall—

(1) identify projects of research on women's health that should be conducted or supported by the national research institutes;

(2) identify multidisciplinary research relating to research on women's health that should be so conducted or supported;

(3) carry out paragraphs (1) and (2) with respect to the aging process in women, with priority given to menopause;

(4) promote coordination and collaboration among entities conducting research identified under any of paragraphs (1) through (3);

(5) encourage the conduct of such research by entities receiving funds from the national research institutes;

(6) recommend an agenda for conducting and supporting such research;

(7) promote the sufficient allocation of the resources of the national research institutes for conducting and supporting such research;

(8) assist in the administration of section 492B with respect to the inclusion of women as subjects in clinical research; and

(9) prepare the report required in section 486B.

(c) COORDINATING COMMITTEE.—

(1) In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (in this subsection referred to as the "Coordinating Committee").

(2) The Coordinating Committee shall be composed of the Directors of the national research institutes (or the designees of the Directors).

(3) The Director of the Office shall serve as the chair of the Coordinating Committee.

(4) With respect to research on women's health, the Coordinating Committee shall assist the Director of the Office in—

(A) identifying the need for such research, and making an estimate each fiscal year of the funds needed to adequately support the research;

(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities;

(C) supporting the development of methodologies to determine the circumstances in which obtaining data specific to women (including data relating to the age of women and the membership of women in ethnic or racial groups) is an appropriate function of clinical trials of treatments and therapies;

(D) supporting the development and expansion of clinical trials of treatments and therapies for which obtaining such data has been determined to be an appropriate function; and

(E) encouraging the national research institutes to conduct and support such research, including such clinical trials.

(d) ADVISORY COMMITTEE.—

(1) In carrying out subsection (b), the Director of the Office shall establish an advisory committee to be known as the Advisory Committee on Research on Women's Health (in this subsection referred to as the "Advisory Committee").

(2) The Advisory Committee shall be composed of no fewer than 12, and not more than 18 individuals, who are not officers or employees of the Federal Government. The Director of the Office shall make appointments to the Advisory Committee from among physicians, practitioners, scientists, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on

research on women's health. A majority of the members of the Advisory Committee shall be women.

(3) The Director of the Office shall serve as the chair of the Advisory Committee.

(4) The Advisory Committee shall—

(A) advise the Director of the Office on appropriate research activities to be undertaken by the national research institutes with respect to—

(i) research on women's health;

(ii) research on gender differences in clinical drug trials, including responses to pharmacological drugs;

(iii) research on gender differences in disease etiology, course, and treatment;

(iv) research on obstetrical and gynecological health conditions, diseases, and treatments; and

(v) research on women's health conditions which require a multidisciplinary approach;

(B) report to the Director of the Office on such research;

(C) provide recommendations to such Director regarding activities of the Office (including recommendations on the development of the methodologies described in subsection (c)(4)(C) and recommendations on priorities in carrying out research described in subparagraph (A)); and

(D) assist in monitoring compliance with section 492B regarding the inclusion of women in clinical research.

(5)(A) The Advisory Committee shall prepare a biennial report describing the activities of the Committee, including findings made by the Committee regarding—

(i) compliance with section 492B;

(ii) the extent of expenditures made for research on women's health by the agencies of the National Institutes of Health; and

(iii) the level of funding needed for such research.

(B) The report required in subparagraph (A) shall be submitted to the Director of NIH for inclusion in the report required in section 403.

(e) REPRESENTATION OF WOMEN AMONG RESEARCHERS.—The Secretary, acting through the Assistant Secretary for Personnel and in collaboration with the Director of the Office, shall determine the extent to which women are represented among senior physicians and scientists of the national research institutes and among physicians and scientists conducting research with funds provided by such institutes, and as appropriate, carry out activities to increase the extent of such representation.

(f) DEFINITIONS.—For purposes of this part:

(1) The term "women's health conditions", with respect to women of all age, ethnic, and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)—

(A) unique to, more serious, or more prevalent in women;

(B) for which the factors of medical risk or types of medical intervention are different for women, or for which

it is unknown whether such factors or types are different for women; or

(C) with respect to which there has been insufficient clinical research involving women as subjects or insufficient clinical data on women.

(2) The term "research on women's health" means research on women's health conditions, including research on preventing such conditions.

SEC. 486A. [287d-1] NATIONAL DATA SYSTEM AND CLEARINGHOUSE ON RESEARCH ON WOMEN'S HEALTH.

(a) DATA SYSTEM.—

(1) The Director of NIH, in consultation with the Director of the Office and the Director of the National Library of Medicine, shall establish a data system for the collection, storage, analysis, retrieval, and dissemination of information regarding research on women's health that is conducted or supported by the national research institutes. Information from the data system shall be available through information systems available to health care professionals and providers, researchers, and members of the public.

(2) The data system established under paragraph (1) shall include a registry of clinical trials of experimental treatments that have been developed for research on women's health. Such registry shall include information on subject eligibility criteria, sex, age, ethnicity or race, and the location of the trial site or sites. Principal investigators of such clinical trials shall provide this information to the registry within 30 days after it is available. Once a trial has been completed, the principal investigator shall provide the registry with information pertaining to the results, including potential toxicities or adverse effects associated with the experimental treatment or treatments evaluated.

(b) CLEARINGHOUSE.—The Director of NIH, in consultation with the Director of the Office and with the National Library of Medicine, shall establish, maintain, and operate a program to provide information on research and prevention activities of the national research institutes that relate to research on women's health.

SEC. 486B. [287d-2] BIENNIAL REPORT.

(a) IN GENERAL.—With respect to research on women's health, the Director of the Office shall, not later than February 1, 1994, and biennially thereafter, prepare a report—

(1) describing and evaluating the progress made during the preceding 2 fiscal years in research and treatment conducted or supported by the National Institutes of Health;

(2) describing and analyzing the professional status of women physicians and scientists of such Institutes, including the identification of problems and barriers regarding advancements;

(3) summarizing and analyzing expenditures made by the agencies of such Institutes (and by such Office) during the preceding 2 fiscal years; and

(4) making such recommendations for legislative and administrative initiatives as the Director of the Office determines to be appropriate.

(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR OF NIH.—The Director of the Office shall submit each report prepared under subsection (a) to the Director of NIH for inclusion in the report submitted to the President and the Congress under section 403.

PART G—AWARDS AND TRAINING

NATIONAL RESEARCH SERVICE AWARDS

SEC. 487. [288] (a)(1) The Secretary shall—

(A) provide National Research Service Awards for—

(i) biomedical and behavioral research at the National Institutes of Health in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the National Institutes of Health and Administration¹ are directed;

(ii) training at the National Institutes of Health and at the Administration¹ of individuals to undertake such research;

(iii) biomedical and behavioral research and health services research (including research in primary medical care) at public and nonprofit private entities; and

(iv) pre-doctoral and post-doctoral training at public and private institutions of individuals to undertake biomedical and behavioral research;

(B) make grants to public and nonprofit private institutions to enable such institutions to make National Research Service Awards for research (and training to undertake biomedical and behavioral research) in the matters described in subparagraph (A)(i) to individuals selected by such institutions; and

(C) provide contracts for scholarships and loan repayments in accordance with sections 487D and 487E, subject to providing not more than an aggregate 50 such contracts during the fiscal years 1994 through 1996.

A reference in this subsection to the National Institutes of Health shall be considered to include the institutes, agencies, divisions, and bureaus included in the National Institutes of Health or under the Administration,¹ as the case may be.

(2) National Research Service Awards may not be used to support residency training of physicians and other health professionals.

(3) In awarding National Research Service Awards under this section, the Secretary shall take account of the Nation's overall need for biomedical research personnel by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

(4) The Secretary shall carry out paragraph (1) in a manner that will result in the recruitment of women, and individuals from

¹ So in law. Section 163(b)(4)(B) of Public Law 102-321 (106 Stat. 376) struck a reference in paragraph (1) to the former Alcohol, Drug Abuse, and Mental Health Administration, but failed to conform related references.

disadvantaged backgrounds (including racial and ethnic minorities), into fields of biomedical or behavioral research and in the provision of research training to women and such individuals.

(b)(1) No National Research Service Award may be made by the Secretary to any individual unless—

(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c); and

(C) in the case of a National Research Service Award for a purpose described in subsection (a)(1)(A)(iii), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institution at which the research or training under the award will be conducted.

An application for an award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

(2) The making of grants under subsection (a)(1)(B) for National Research Service Awards shall be subject to review and approval by the appropriate advisory councils within the Department of Health and Human Services (A) whose activities relate to the research or training under the awards, or (B) for the entity at which such research or training will be conducted.

(3) No grant may be made under subsection (a)(1)(B) unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section (other than paragraph (1)), National Research Service Awards made under a grant under subsection (a)(1)(B) shall be made in accordance with such regulations as the Secretary shall prescribe.

(4) The period of any National Research Service Award made to any individual under subsection (a) may not exceed—

(A) five years in the aggregate for pre-doctoral training; and

(B) three years in the aggregate for post-doctoral training; unless the Secretary for good cause shown waives the application of such limit to such individual.

(5) National Research Service Awards shall provide for such stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), adjusted periodically to reflect increases in the cost of living, for the recipients of the awards as the Secretary may deem necessary. A National Research Service Award made to an individual for research or research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable

costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

(c)(1) Each individual who is awarded a National Research Service Award for postdoctoral research training shall, in accordance with paragraph (3), engage in research training, research, or teaching that is health-related (or any combination thereof) for the period specified in paragraph (2). Such period shall be served in accordance with the usual patterns of scientific employment.

(2)(A) The period referred to in paragraph (1) is 12 months, or one month for each month for which the individual involved receives a National Research Service Award for postdoctoral research training, whichever is less.

(B) With respect to postdoctoral research training, in any case in which an individual receives a National Research Service Award for more than 12 months, the 13th month and each subsequent month of performing activities under the Award shall be considered to be activities engaged in toward satisfaction of the requirement established in paragraph (1) regarding a period of service.

(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's award, as the Secretary shall by regulation prescribe. The Secretary shall by regulation prescribe the type of research and teaching in which an individual may engage to comply with such requirement and such other requirements respecting research and teaching as the Secretary considers appropriate.

(4)(A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph (3), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A = \phi \left(\frac{t-s}{t} \right)$$

in which "A" is the amount the United States is entitled to recover; "φ" is the sum of the total amount paid under one or more National Research Service Awards to such individual; "t" is the total number of months in such individual's service obligation; and "s" is the number of months of such obligation served by such individual in accordance with paragraphs (1) and (2) of this subsection.

(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any National Research Service Award is paid, there shall accrue to the United States interest on such amount at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount.

(5)(A) Any obligation of an individual under paragraph (1) shall be canceled upon the death of such individual.

(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve substantial hardship to such individual or would be against equity and good conscience.

(d) For the purpose of carrying out this section, there are authorized to be appropriated \$400,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Of the amounts appropriated under this subsection—

(1) not less than 15 percent shall be made available for payments under National Research Service Awards provided by the Secretary under subsection (a)(1)(A);

(2) not less than 50 percent shall be made available for grants under subsection (a)(1)(B) for National Research Service Awards;

(3) 1 percent shall be made available to the Secretary, acting through the Administrator of the Health Resources and Services Administration, for payments under National Research Service Awards which (A) are made to individuals affiliated with entities which have received grants or contracts under section 747, 748, or 749, and (B) are for research in primary medical care; and 1 percent shall be made available for payments under National Research Service Awards made for health services research by the Agency for Health Care Policy and Research under section 304(a); and

(4) not more than 4 percent may be obligated for National Research Service Awards for periods of three months or less.

LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

SEC. 487A. [288-1] (a) IN GENERAL.—The Secretary shall carry out a program of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct, as employees of the National Institutes of Health, research with respect to acquired immune deficiency syndrome in consideration of the Federal Government agreeing to repay, for each year of such service, not more than \$20,000 of the principal and interest of the educational loans of such health professionals.

(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO
CONTRACEPTION AND INFERTILITY

SEC. 487B. [288-2] (a) The Secretary, in consultation with the Director of the National Institute of Child Health and Human Development, shall establish a program of entering into contracts with qualified health professionals (including graduate students) under which such health professionals agree to conduct research with respect to contraception, or with respect to infertility, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than \$20,000 of the principal and interest of the educational loans of such health professionals.

(b) The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with subsection (a) of this section, apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

(c) Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were made available.

LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY

SEC. 487C. [288-3] (a) IN GENERAL.—

(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the National Institutes of Health, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than \$20,000 of the principal and interest of the educational loans of such health professionals.

(2) LIMITATION.—The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee of the National Institutes of Health for purposes of paragraph (1) for a period of not less than 3 years.

(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS
NEEDED BY NATIONAL RESEARCH INSTITUTES

SEC. 487D. [288-4] (a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH, may carry out a program of entering into contracts with individuals described in paragraph (2) under which—

(A) the Director of NIH agrees to provide to the individuals scholarships for pursuing, as undergraduates at accredited institutions of higher education, academic programs appropriate for careers in professions needed by the National Institutes of Health; and

(B) the individuals agree to serve as employees of the National Institutes of Health, for the period described in subsection (c), in positions that are needed by the National Institutes of Health and for which the individuals are qualified.

(2) INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS.—The individuals referred to in paragraph (1) are individuals who—

(A) are enrolled or accepted for enrollment as full-time undergraduates at accredited institutions of higher education; and

(B) are from disadvantaged backgrounds.

(b) FACILITATION OF INTEREST OF STUDENTS IN CAREERS AT NATIONAL INSTITUTES OF HEALTH.—In providing employment to individuals pursuant to contracts under subsection (a)(1), the Director of NIH shall carry out activities to facilitate the interest of the individuals in pursuing careers as employees of the National Institutes of Health.

(c) PERIOD OF OBLIGATED SERVICE.—

(1) DURATION OF SERVICE.—For purposes of subparagraph (B) of subsection (a)(1), the period of service for which an individual is obligated to serve as an employee of the National Institutes of Health is, subject to paragraph (2)(A), 12 months for each academic year for which the scholarship under such subsection is provided.

(2) SCHEDULE FOR SERVICE.—

(A) Subject to subparagraph (B), the Director of NIH may not provide a scholarship under subsection (a) unless the individual applying for the scholarship agrees that—

(i) the individual will serve as an employee of the National Institutes of Health full-time for not less than 10 consecutive weeks of each year during which the individual is attending the educational institution involved and receiving such a scholarship;

(ii) the period of service as such an employee that the individual is obligated to provide under clause (i) is in addition to the period of service as such an employee that the individual is obligated to provide under subsection (a)(1)(B); and

(iii) not later than 60 days after obtaining the educational degree involved, the individual will begin serving full-time as such an employee in satisfaction of the period of service that the individual is obligated to provide under subsection (a)(1)(B).

(B) The Director of NIH may defer the obligation of an individual to provide a period of service under subsection (a)(1)(B), if the Director determines that such a deferral is appropriate.

(3) APPLICABILITY OF CERTAIN PROVISIONS RELATING TO APPOINTMENT AND COMPENSATION.—For any period in which an individual provides service as an employee of the National Institutes of Health in satisfaction of the obligation of the individual under subsection (a)(1)(B) or paragraph (2)(A)(i), the individual may be appointed as such an employee without regard to the provisions of title 5, United States Code, relating to appointment and compensation.

(d) PROVISIONS REGARDING SCHOLARSHIP.—

(1) APPROVAL OF ACADEMIC PROGRAM.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless—

(A) the individual applying for the scholarship has submitted to the Director a proposed academic program for the year and the Director has approved the program; and

(B) the individual agrees that the program will not be altered without the approval of the Director.

(2) ACADEMIC STANDING.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless the individual applying for the scholarship agrees to maintain an acceptable level of academic standing, as determined by the educational institution involved in accordance with regulations issued by the Secretary.

(3) LIMITATION ON AMOUNT.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year in an amount exceeding \$20,000.

(4) AUTHORIZED USES.—A scholarship provided under subsection (a) may be expended only for tuition expenses, other reasonable educational expenses, and reasonable living expenses incurred in attending the school involved.

(5) CONTRACT REGARDING DIRECT PAYMENTS TO INSTITUTION.—In the case of an institution of higher education with respect to which a scholarship under subsection (a) is provided, the Director of NIH may enter into a contract with the institution under which the amounts provided in the scholarship for tuition and other educational expenses are paid directly to the institution.

(e) PENALTIES FOR BREACH OF SCHOLARSHIP CONTRACT.—The provisions of section 338E shall apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

(f) REQUIREMENT OF APPLICATION.—The Director of NIH may not provide a scholarship under subsection (a) unless an application for the scholarship is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

(g) AVAILABILITY OF AUTHORIZATION OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for scholarships under this

section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS
FROM DISADVANTAGED BACKGROUNDS

SEC. 487E. [288-5] (a) IMPLEMENTATION OF PROGRAM.—

(1) IN GENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH may, subject to paragraph (2), carry out a program of entering into contracts with appropriately qualified health professionals who are from disadvantaged backgrounds under which such health professionals agree to conduct clinical research as employees of the National Institutes of Health in consideration of the Federal Government agreeing to pay, for each year of such service, not more than \$20,000 of the principal and interest of the educational loans of the health professionals.

(2) LIMITATION.—The Director of NIH may not enter into a contract with a health professional pursuant to paragraph (1) unless such professional has a substantial amount of education loans relative to income.

(3) APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—Except to the extent inconsistent with this section, the provisions of sections 338C and 338E shall apply to the program established in paragraph (1) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

(b) AVAILABILITY OF AUTHORIZATION OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for contracts under subsection (a) shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

VISITING SCIENTIST AWARDS

SEC. 488. [288a] (a) The Secretary may make awards (hereafter in this section referred to as "Visiting Scientist Awards") to outstanding scientists who agree to serve as visiting scientists at institutions of postsecondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for

and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe.

STUDIES RESPECTING BIOMEDICAL AND BEHAVIORAL RESEARCH
PERSONNEL

SEC. 489. [288b] (a) The Secretary shall, in accordance with subsection (b), arrange for the conduct of a continuing study to—

(1) establish (A) the Nation's overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel;

(2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this Act, at or through national research institutes under the National Institutes of Health, and (B) other current training programs available for the training of such personnel;

(3) identify the kinds of research positions available to and held by individuals completing such programs;

(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

(b)(1) The Secretary shall request the National Academy of Sciences to conduct the study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of such study.

(2) If the National Academy of Sciences is unwilling to conduct such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in subsection (c).

(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of NIH.

(c) A report on the results of the study required under subsection (a) shall be submitted by the Secretary to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least once every four years.

PART H—GENERAL PROVISIONS

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

SEC. 491. [289] (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such violations.

PEER REVIEW REQUIREMENTS

SEC. 492. [289a] (a)(1) The Secretary, acting through the Director of NIH, shall by regulation require appropriate technical and scientific peer review of—

(A) applications made for grants and cooperative agreements under this Act for biomedical and behavioral research; and

(B) applications made for biomedical and behavioral research and development contracts to be administered through the National Institutes of Health.

(2) Regulations promulgated under paragraph (1) shall require that the review of applications made for grants, contracts, and cooperative agreements required by the regulations be conducted—

(A) to the extent practical, in a manner consistent with the system for technical and scientific peer review applicable on the date of the date of enactment of the Health Research Extension Act of 1985 to grants under this Act for biomedical and behavioral research, and

(B) to the extent practical, by technical and scientific peer review groups performing such review on or before such date, and shall authorize such review to be conducted by groups appointed under sections 402(b)(6) and 405(c)(3).

(b) The Director of NIH shall establish procedures for periodic technical and scientific peer review of research at the National Institutes of Health. Such procedures shall require that—

(1) the reviewing entity be provided a written description of the research to be reviewed, and

(2) the reviewing entity provide the advisory council of the national research institute involved with such description and the results of the review by the entity, and shall authorize such review to be conducted by groups appointed under sections 402(b)(6) and 405(c)(3).

(c)(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding compliance with section 492B.

(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 492B, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.

CERTAIN PROVISIONS REGARDING REVIEW AND APPROVAL OF PROPOSALS FOR RESEARCH

SEC. 492A. [289a-1] (a) REVIEW AS PRECONDITION TO RESEARCH.—

(1) PROTECTION OF HUMAN RESEARCH SUBJECTS.—

(A) In the case of any application submitted to the Secretary for financial assistance to conduct research, the Secretary may not approve or fund any application that is subject to review under section 491(a) by an Institutional Review Board unless the application has undergone review in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting such review.

(B) In the case of research that is subject to review under procedures established by the Secretary for the protection of human subjects in clinical research conducted by the National Institutes of Health, the Secretary may not authorize the conduct of the research unless the research has, pursuant to such procedures, been recommended for approval.

(2) PEER REVIEW.—In the case of any proposal for the National Institutes of Health to conduct or support research, the Secretary may not approve or fund any proposal that is subject to technical and scientific peer review under section 492 unless the proposal has undergone such review in accordance with such section and has been recommended for approval by a majority of the members of the entity conducting such review.

(b) ETHICAL REVIEW OF RESEARCH.—

(1) PROCEDURES REGARDING WITHHOLDING OF FUNDS.—If research has been recommended for approval for purposes of subsection (a), the Secretary may not withhold funds for the research because of ethical considerations unless—

(A) the Secretary convenes an advisory board in accordance with paragraph (5) to study such considerations; and

(B)(i) the majority of the advisory board recommends that, because of such considerations, the Secretary withhold funds for the research; or

(ii) the majority of such board recommends that the Secretary not withhold funds for the research because of such considerations, but the Secretary finds, on the basis of the report submitted under paragraph (5)(B)(ii), that the recommendation is arbitrary and capricious.

(2) RULES OF CONSTRUCTION.—Paragraph (1) may not be construed as prohibiting the Secretary from withholding funds for research on the basis of—

(A) the inadequacy of the qualifications of the entities that would be involved with the conduct of the research (including the entity that would directly receive the funds from the Secretary), subject to the condition that, with respect to the process of review through which the research was recommended for approval for purposes of subsection (a), all findings regarding such qualifications made in such process are conclusive; or

(B) the priorities established by the Secretary for the allocation of funds among projects of research that have been so recommended.

(3) APPLICABILITY.—The limitation established in paragraph (1) regarding the authority to withhold funds because of ethical considerations shall apply without regard to whether the withholding of funds on such basis is characterized as a disapproval, a moratorium, a prohibition, or other characterization.

(4) PRELIMINARY MATTERS REGARDING USE OF PROCEDURES.—

(A) If the Secretary makes a determination that an advisory board should be convened for purposes of paragraph (1), the Secretary shall, through a statement published in the Federal Register, announce the intention of the Secretary to convene such a board.

(B) A statement issued under subparagraph (A) shall include a request that interested individuals submit to the Secretary recommendations specifying the particular individuals who should be appointed to the advisory board involved. The Secretary shall consider such recommendations in making appointments to the board.

(C) The Secretary may not make appointments to an advisory board under paragraph (1) until the expiration of the 30-day period beginning on the date on which the statement required in subparagraph (A) is made with respect to the board.

(5) ETHICS ADVISORY BOARDS.—

(A) Any advisory board convened for purposes of paragraph (1) shall be known as an ethics advisory board (in this paragraph referred to as an "ethics board").

(B)(i) An ethics board shall advise, consult with, and make recommendations to the Secretary regarding the ethics of the project of biomedical or behavioral research with respect to which the board has been convened.

(ii) Not later than 180 days after the date on which the statement required in paragraph (4)(A) is made with respect to an ethics board, the board shall submit to the Secretary, and to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report describing the findings of the board regarding the project of research involved and making a recommendation under clause (i) of whether the Secretary should or should not withhold funds for the project. The report shall include the information considered in making the findings.

(C) An ethics board shall be composed of no fewer than 14, and no more than 20, individuals who are not officers or employees of the United States. The Secretary shall make appointments to the board from among individuals with special qualifications and competence to provide advice and recommendations regarding ethical matters in biomedical and behavioral research. Of the members of the board—

(i) no fewer than 1 shall be an attorney;

(ii) no fewer than 1 shall be an ethicist;

(iii) no fewer than 1 shall be a practicing physician;

(iv) no fewer than 1 shall be a theologian; and

(v) no fewer than one-third, and no more than one-half, shall be scientists with substantial accomplishments in biomedical or behavioral research.

(D) The term of service as a member of an ethics board shall be for the life of the board. If such a member does not serve the full term of such service, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(E) A member of an ethics board shall be subject to removal from the board by the Secretary for neglect of duty or malfeasance or for other good cause shown.

(F) The Secretary shall designate an individual from among the members of an ethics board to serve as the chair of the board.

(G) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall conduct inquiries and hold public hearings.

(H) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall have access to all relevant information possessed by the Department of Health and Human Services, or available to the Secretary from other agencies.

(I) Members of an ethics board shall receive compensation for each day engaged in carrying out the duties of the board, including time engaged in traveling for purposes of such duties. Such compensation may not be provided in an amount in excess of the maximum rate of basic pay payable for GS-18 of the General Schedule.

(J) The Secretary, acting through the Director of the National Institutes of Health, shall provide to each ethics board reasonable staff and assistance to carry out the duties of the board.

(K) An ethics board shall terminate 30 days after the date on which the report required in subparagraph (B)(ii) is submitted to the Secretary and the congressional committees specified in such subparagraph.

(6) DEFINITION.—For purposes of this subsection, the term “ethical considerations” means considerations as to whether the nature of the research involved is such that it is unethical to conduct or support the research.

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

SEC. 492B. [289a–2] (a) REQUIREMENT OF INCLUSION.—

(1) IN GENERAL.—In conducting or supporting clinical research for purposes of this title, the Director of NIH shall, subject to subsection (b), ensure that—

(A) women are included as subjects in each project of such research; and

(B) members of minority groups are included as subjects in such research.

(2) OUTREACH REGARDING PARTICIPATION AS SUBJECTS.—The Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall conduct or support outreach programs for the recruitment of women and members of minority groups as subjects in projects of clinical research.

(b) INAPPLICABILITY OF REQUIREMENT.—The requirement established in subsection (a) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

(1) is inappropriate with respect to the health of the subjects;

(2) is inappropriate with respect to the purpose of the research; or

(3) is inappropriate under such other circumstances as the Director of NIH may designate.

(c) DESIGN OF CLINICAL TRIALS.—In the case of any clinical trial in which women or members of minority groups will under subsection (a) be included as subjects, the Director of NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

(d) GUIDELINES.—

(1) IN GENERAL.—Subject to paragraph (2), the Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall establish guidelines regarding the requirements of this section. The guidelines shall include guidelines regarding—

(A) the circumstances under which the inclusion of women and minorities as subjects in projects of clinical research is inappropriate for purposes of subsection (b);

(B) the manner in which clinical trials are required to be designed and carried out for purposes of subsection (c); and

(C) the operation of outreach programs under subsection (a).

(2) CERTAIN PROVISIONS.—With respect to the circumstances under which the inclusion of women or members of minority groups (as the case may be) as subjects in a project of clinical research is inappropriate for purposes of subsection (b), the following applies to guidelines under paragraph (1):

(A)(i) In the case of a clinical trial, the guidelines shall provide that the costs of such inclusion in the trial is not a permissible consideration in determining whether such inclusion is inappropriate.

(ii) In the case of other projects of clinical research, the guidelines shall provide that the costs of such inclusion in the project is not a permissible consideration in determining whether such inclusion is inappropriate unless the data regarding women or members of minority groups, respectively, that would be obtained in such project (in the event that such inclusion were required) have been or are being obtained through other means that provide data of comparable quality.

(B) In the case of a clinical trial, the guidelines may provide that such inclusion in the trial is not required if there is substantial scientific data demonstrating that there is no significant difference between—

(i) the effects that the variables to be studied in the trial have on women or members of minority groups, respectively; and

(ii) the effects that the variables have on the individuals who would serve as subjects in the trial in the event that such inclusion were not required.

(e) DATE CERTAIN FOR GUIDELINES; APPLICABILITY.—

(1) DATE CERTAIN.—The guidelines required in subsection (d) shall be established and published in the Federal Register not later than 180 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993.

(2) APPLICABILITY.—For fiscal year 1995 and subsequent fiscal years, the Director of NIH may not approve any proposal of clinical research to be conducted or supported by any agency of the National Institutes of Health unless the proposal specifies the manner in which the research will comply with this section.

(f) REPORTS BY ADVISORY COUNCILS.—The advisory council of each national research institute shall prepare biennial reports describing the manner in which the institute has complied with this section. Each such report shall be submitted to the Director of the institute involved for inclusion in the biennial report under section 403.

(g) DEFINITIONS.—For purposes of this section:

(1) The term "project of clinical research" includes a clinical trial.

(2) The term "minority group" includes subpopulations of minority groups. The Director of NIH shall, through the guidelines established under subsection (d), define the terms "minority group" and "subpopulation" for purposes of the preceding sentence.

OFFICE OF RESEARCH INTEGRITY

SEC. 493. [289b] (a) IN GENERAL.—

(1) ESTABLISHMENT OF OFFICE.—Not later than 90 days after the date of enactment of this section, the Secretary shall establish an office to be known as the Office of Research Integrity (referred to in this section as the "Office"), which shall be established as an independent entity in the Department of Health and Human Services.

(2) APPOINTMENT OF DIRECTOR.—The Office shall be headed by a Director, who shall be appointed by the Secretary, be experienced and specially trained in the conduct of research, and have experience in the conduct of investigations of research misconduct. The Secretary shall carry out this section acting through the Director of the Office. The Director shall report to the Secretary.

(3) DEFINITIONS.—

(A) The Secretary shall by regulation establish a definition for the term "research misconduct" for purposes of this section.

(B) For purposes of this section, the term "financial assistance" means a grant, contract, or cooperative agreement.

(b) EXISTENCE OF ADMINISTRATIVE PROCESSES AS CONDITION OF FUNDING FOR RESEARCH.—The Secretary shall by regulation require that each entity that applies for financial assistance under this Act for any project or program that involves the conduct of biomedical or behavioral research submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity;

(2) an agreement that the entity will report to the Director any investigation of alleged research misconduct in connection with projects for which funds have been made available under this Act that appears substantial; and

(3) an agreement that the entity will comply with regulations issued under this section.

(c) PROCESS FOR RESPONSE OF DIRECTOR.—The Secretary shall by regulation establish a process to be followed by the Director for the prompt and appropriate—

(1) response to information provided to the Director respecting research misconduct in connection with projects for which funds have been made available under this Act;

(2) receipt of reports by the Director of such information from recipients of funds under this Act;

(3) conduct of investigations, when appropriate; and

(4) taking of other actions, including appropriate remedies, with respect to such misconduct.

(d) MONITORING BY DIRECTOR.—The Secretary shall by regulation establish procedures for the Director to monitor administrative processes and investigations that have been established or carried out under this section.

(e) PROTECTION OF WHISTLEBLOWERS.—

(1) IN GENERAL.—In the case of any entity required to establish administrative processes under subsection (b), the Secretary shall by regulation establish standards for preventing, and for responding to the occurrence of retaliation by such entity, its officials or agents, against an employee in the terms and conditions of employment in response to the employee having in good faith—

(A) made an allegation that the entity, its officials or agents, has engaged in or failed to adequately respond to an allegation of research misconduct; or

(B) cooperated with an investigation of such an allegation.

(2) MONITORING BY SECRETARY.—The Secretary shall by regulation establish procedures for the Director to monitor the implementation of the standards established by an entity under paragraph (1) for the purpose of determining whether the procedures have been established, and are being utilized, in accordance with the standards established under such paragraph.

(3) NONCOMPLIANCE.—The Secretary shall by regulation establish remedies for noncompliance by an entity, its officials or agents, which has engaged in retaliation in violation of the standards established under paragraph (1). Such remedies may include termination of funding provided by the Secretary for such project or recovery of funding being provided by the Secretary for such project, or other actions as appropriate.

PROTECTION AGAINST FINANCIAL CONFLICTS OF INTEREST IN CERTAIN PROJECTS OF RESEARCH

SEC. 493A. [289b-1] (a) ISSUANCE OF REGULATIONS.—The Secretary shall by regulation define the specific circumstances that constitute the existence of a financial interest in a project on the part of an entity or individual that will, or may be reasonably expected to, create a bias in favor of obtaining results in such project that are consistent with such financial interest. Such definition shall apply uniformly to each entity or individual conducting a research project under this Act. In the case of any entity or individual receiving assistance from the Secretary for a project of research described in subsection (b), the Secretary shall by regulation establish standards for responding to, including managing, reducing, or eliminating, the existence of such a financial interest. The entity may adopt individualized procedures for implementing the standards.

(b) **RELEVANT PROJECTS.**—A project of research referred to in subsection (a) is a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment and for which such entity is receiving assistance from the Secretary.

(c) **IDENTIFYING AND REPORTING TO SECRETARY.**—The Secretary shall by regulation require that each entity described in subsection (a) that applies for assistance under this Act for any project described in subsection (b) submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect an administrative process under subsection (a) to identify financial interests (as defined under subsection (a)) that exist regarding the project; and

(2) an agreement that the entity will report to the Secretary such interests identified by the entity and how any such interests identified by the entity will be managed or eliminated in order that the project in question will be protected from bias that may stem from such interests; and

(3) an agreement that the entity will comply with regulations issued under this section.

(d) **MONITORING OF PROCESS.**—The Secretary shall monitor the establishment and conduct of the administrative process established by an entity pursuant to subsection (a).

(e) **RESPONSE.**—In any case in which the Secretary determines that an entity has failed to comply with subsection (c) regarding a project of research described in subsection (b), the Secretary—

(1) shall require that, as a condition of receiving assistance, the entity disclose the existence of a financial interest (as defined under subsection (a)) in each public presentation of the results of such project; and

(2) may take such other actions as the Secretary determines to be appropriate.

(f) **DEFINITIONS.**—For purposes of this section:

(1) The term “financial interest” includes the receipt of consulting fees or honoraria and the ownership of stock or equity.

(2) The term “assistance”, with respect to conducting a project of research, means a grant, contract, or cooperative agreement.

RESEARCH ON PUBLIC HEALTH EMERGENCIES

SEC. 494. [289c] (a) If the Secretary determines, after consultation with the Director of NIH, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control and Prevention, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of NIH—

(1) shall expedite the review by advisory councils under section 406 and by peer review groups under section 492 of applications for grants for research on such disease or disorder or proposals for contracts for such research;

(2) shall exercise the authority in section 3709 of the Revised Statutes (41 U.S.C. 5) respecting public exigencies to

waive the advertising requirements of such section in the case of proposals for contracts for such research;

(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; and

(4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatment of such disease or disorder that has been developed in research assisted under this section.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.

(b) Not later than 90 days after the end of a fiscal year, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on actions taken under subsection (a) in such fiscal year.

COLLABORATIVE USE OF CERTAIN HEALTH SERVICES RESEARCH FUNDS

SEC. 494A. [289c-1] (a) **IN GENERAL.**—The Secretary shall ensure that amounts made available under subparts 14, 15 and 16 of part C for health services research relating to alcohol abuse and alcoholism, drug abuse and mental health be used collaboratively, as appropriate, and in consultation with the Agency for Health Care Policy Research.

(b) **REPORT.**—Not later than September 30, 1993, and annually thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report concerning the activities carried out with the amounts referred to in subsection (a).

ANIMALS IN RESEARCH

SEC. 495. [289d] (a) The Secretary, acting through the Director of NIH, shall establish guidelines for the following:

(1) The proper care of animals to be used in biomedical and behavioral research.

(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall require—

(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

(3) The organization and operation of animal care committees in accordance with subsection (b).

(b)(1) Guidelines of the Secretary under subsection (a)(3) shall require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act (including the National Institutes of Health and the national

research institutes) to assure compliance with the guidelines established under subsection (a).

(2) Each animal care committee shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than three members, and shall include at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

(3) Each animal care committee of a research entity shall—

(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semi-annually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment;

(B) keep appropriate records of reviews conducted under subparagraph (A); and

(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

Reports filed under subparagraph (C) shall include any minority views filed by members of the committee.

(c) The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in its application or contract proposal, submitted after the expiration of the twelve-month period beginning on the date of enactment of this section—

(1) assurances satisfactory to the Director of NIH that—

(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress; and

(2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract.

Notwithstanding subsection (a)(2) of section 553 of title 5, United States Code, regulations under this subsection shall be promulgated in accordance with the notice and comment requirements of such section.

(d) If the Director of NIH determines that—

(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this title do

not meet applicable guidelines established under subsection (a);

(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

(3) no action has been taken by the entity to correct such conditions;

the Director of NIH shall suspend or revoke such grant or contract under such conditions as the Director determines appropriate.

(e) No guideline or regulation promulgated under subsection (a) or (c) may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential.

USE OF APPROPRIATIONS UNDER THIS TITLE

SEC. 496. [289e] (a) Appropriations to carry out the purposes of this title, unless otherwise expressly provided, may be expended in the District of Columbia for—

(1) personal services;

(2) stenographic recording and translating services;

(3) travel expenses (including the expenses of attendance at meetings when specifically authorized by the Secretary);

(4) rental;

(5) supplies and equipment;

(6) purchase and exchange of medical books, books of reference, directories, periodicals, newspapers, and press clippings;

(7) purchase, operation, and maintenance of passenger motor vehicles;

(8) printing and binding (in addition to that otherwise provided by law); and

(9) all other necessary expenses in carrying out this title.

Such appropriations may be expended by contract if deemed necessary, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

(b)(1) None of the amounts appropriated under this Act for the purposes of this title may be obligated for the construction of facilities (including the acquisition of land) unless a provision of this title establishes express authority for such purpose and unless the Act making appropriations under such provision specifies that the amounts appropriated are available for such purpose.

(2) Any grants, cooperative agreements, or contracts authorized in this title for the construction of facilities may be awarded only on a competitive basis.

GIFTS

SEC. 497. [289f] The Secretary may, in accordance with section 231, accept conditional gifts for the National Institutes of Health or a national research institute or for the acquisition of grounds or for the erection, equipment, or maintenance of facilities for the National Institutes of Health or a national research institute. Donations of \$50,000 or over for the National Institutes of Health or a national research institute for carrying out the pur-

poses of this title may be acknowledged by the establishment within the National Institutes of Health or a national research institute of suitable memorials to the donors.

FETAL RESEARCH

SEC. 498. [289g] (a) The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—

(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

(b) In administering the regulations for the protection of human research subjects which—

(1) apply to research conducted or supported by the Secretary;

(2) involve living human fetuses in utero; and

(3) are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations;

or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

SEC. 498A. [289g-1] (a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—The Secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes.

(2) SOURCE OF TISSUE.—Human fetal tissue may be used in research carried out under paragraph (1) regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.

(b) INFORMED CONSENT OF DONOR.—

(1) IN GENERAL.—In research carried out under subsection (a), human fetal tissue may be used only if the woman providing the tissue makes a statement, made in writing and signed by the woman, declaring that—

(A) the woman donates the fetal tissue for use in research described in subsection (a);

(B) the donation is made without any restriction regarding the identity of individuals who may be the recipients of transplantations of the tissue; and

(C) the woman has not been informed of the identity of any such individuals.

(2) ADDITIONAL STATEMENT.—In research carried out under subsection (a), human fetal tissue may be used only if the at-

tending physician with respect to obtaining the tissue from the woman involved makes a statement, made in writing and signed by the physician, declaring that—

(A) in the case of tissue obtained pursuant to an induced abortion—

(i) the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for a donation of the tissue for use in such research;

(ii) no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; and

(iii) the abortion was performed in accordance with applicable State law;

(B) the tissue has been donated by the woman in accordance with paragraph (1); and

(C) full disclosure has been provided to the woman with regard to—

(i) such physician's interest, if any, in the research to be conducted with the tissue; and

(ii) any known medical risks to the woman or risks to her privacy that might be associated with the donation of the tissue and that are in addition to risks of such type that are associated with the woman's medical care.

(c) INFORMED CONSENT OF RESEARCHER AND DONEE.—In research carried out under subsection (a), human fetal tissue may be used only if the individual with the principal responsibility for conducting the research involved makes a statement, made in writing and signed by the individual, declaring that the individual—

(1) is aware that—

(A) the tissue is human fetal tissue;

(B) the tissue may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and

(C) the tissue was donated for research purposes;

(2) has provided such information to other individuals with responsibilities regarding the research;

(3) will require, prior to obtaining the consent of an individual to be a recipient of a transplantation of the tissue, written acknowledgment of receipt of such information by such recipient; and

(4) has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy made solely for the purposes of the research.

(d) AVAILABILITY OF STATEMENTS FOR AUDIT.—

(1) IN GENERAL.—In research carried out under subsection (a), human fetal tissue may be used only if the head of the agency or other entity conducting the research involved certifies to the Secretary that the statements required under subsections (b)(2) and (c) will be available for audit by the Secretary.

(2) CONFIDENTIALITY OF AUDIT.—Any audit conducted by the Secretary pursuant to paragraph (1) shall be conducted in a confidential manner to protect the privacy rights of the indi-

viduals and entities involved in such research, including such individuals and entities involved in the donation, transfer, receipt, or transplantation of human fetal tissue. With respect to any material or information obtained pursuant to such audit, the Secretary shall—

(A) use such material or information only for the purposes of verifying compliance with the requirements of this section;

(B) not disclose or publish such material or information, except where required by Federal law, in which case such material or information shall be coded in a manner such that the identities of such individuals and entities are protected; and

(C) not maintain such material or information after completion of such audit, except where necessary for the purposes of such audit.

(e) APPLICABILITY OF STATE AND LOCAL LAW.—

(1) RESEARCH CONDUCTED BY RECIPIENTS OF ASSISTANCE.—The Secretary may not provide support for research under subsection (a) unless the applicant for the financial assistance involved agrees to conduct the research in accordance with applicable State law.

(2) RESEARCH CONDUCTED BY SECRETARY.—The Secretary may conduct research under subsection (a) only in accordance with applicable State and local law.

(f) REPORT.—The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this section during the preceding fiscal year, including a description of whether and to what extent research under subsection (a) has been conducted in accordance with this section.

(g) DEFINITION.—For purposes of this section, the term “human fetal tissue” means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.

PROHIBITIONS REGARDING HUMAN FETAL TISSUE

SEC. 498B. [289g-2] (a) PURCHASE OF TISSUE.—It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.

(b) SOLICITATION OR ACCEPTANCE OF TISSUE AS DIRECTED DONATION FOR USE IN TRANSPLANTATION.—It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, the tissue will be or is obtained pursuant to an induced abortion, and—

(1) the donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual;

(2) the donated tissue will be transplanted into a relative of the donating individual; or

(3) the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.

(c) CRIMINAL PENALTIES FOR VIOLATIONS.—

(1) IN GENERAL.—Any person who violates subsection (a) or (b) shall be fined in accordance with title 18, United States Code, subject to paragraph (2), or imprisoned for not more than 10 years, or both.

(2) PENALTIES APPLICABLE TO PERSONS RECEIVING CONSIDERATION.—With respect to the imposition of a fine under paragraph (1), if the person involved violates subsection (a) or (b)(3), a fine shall be imposed in an amount not less than twice the amount of the valuable consideration received.

(d) DEFINITIONS.—For purposes of this section:

(1) The term “human fetal tissue” has the meaning given such term in section 498A(f).

(2) The term “interstate commerce” has the meaning given such term in section 201(b) of the Federal Food, Drug, and Cosmetic Act.

(3) The term “valuable consideration” does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

PART I—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

SEC. 499. [290b] ESTABLISHMENT AND DUTIES OF FOUNDATION.

(a) IN GENERAL.—The Secretary shall, acting through the Director of NIH, establish a nonprofit corporation to be known as the National Foundation for Biomedical Research (hereafter in this section referred to as the “Foundation”). The Foundation shall not be an agency or instrumentality of the United States Government.

(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation shall be to support the National Institutes of Health in its mission, and to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations.

(c) CERTAIN ACTIVITIES OF FOUNDATION.—

(1) IN GENERAL.—In carrying out subsection (b), the Foundation may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of the following activities with respect to the purpose described in such subsection:

(A) A program to provide and administer endowed positions that are associated with the research program of the National Institutes of Health. Such endowments may be expended for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the endowed positions.

(B) A program to provide and administer fellowships and grants to research personnel in order to work and study in association with the National Institutes of Health. Such fellowships and grants may include stipends, travel, health insurance benefits and other appropriate expenses.

The recipients of fellowships shall be selected by the donors and the Foundation upon the recommendation of the National Institutes of Health employees in the laboratory where the fellow would serve, and shall be subject to the agreement of the Director of the National Institutes of Health and the Executive Director of the Foundation.

(C) Supplementary programs to provide for—

(i) scientists of other countries to serve in research capacities in the United States in association with the National Institutes of Health or elsewhere, or opportunities for employees of the National Institutes of Health or other public health officials in the United States to serve in such capacities in other countries, or both;

(ii) the conduct and support of studies, projects, and research, which may include stipends, travel and other support for personnel in collaboration with national and international non-profit and for-profit organizations;

(iii) the conduct and support of forums, meetings, conferences, courses, and training workshops that may include undergraduate, graduate, post-graduate, and post-doctoral accredited courses and the maintenance of accreditation of such courses by the Foundation at the State and national level for college or continuing education credits or for degrees;

(iv) programs to support and encourage teachers and students of science at all levels of education and programs for the general public which promote the understanding of science;

(v) programs for writing, editing, printing, publishing, and vending of books and other materials; and

(vi) the conduct of other activities to carry out and support the purpose described in subsection (b).

(2) FEES.—The Foundation may assess fees for the provision of professional, administrative and management services by the Foundation in amounts determined reasonable and appropriate by the Executive Director.

(3) AUTHORITY OF FOUNDATION.—The Foundation shall be the sole entity responsible for carrying out the activities described in this subsection.

(d) BOARD OF DIRECTORS.—

(1) COMPOSITION.—

(A) The Foundation shall have a Board of Directors (hereafter referred to in this section as the "Board"), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

(B) The ex officio members of the Board shall be—

(i) the Chairman and ranking minority member of the Subcommittee on Health and the Environment (Committee on Energy and Commerce) or their designees, in the case of the House of Representatives;

(ii) the Chairman and ranking minority member of the Committee on Labor and Human Resources or their designees, in the case of the Senate; and

(iii) the Director of the National Institutes of Health.

(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board 11 individuals from among a list of candidates to be provided by the National Academy of Science. Of such appointed members—

(i) 4 shall be representative of the general biomedical field;

(ii) 2 shall be representatives of the general biobehavioral field; and

(iii) 5 shall be representatives of the general public.

(D)(i) Not later than 30 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993, the Director of the National Institutes of Health shall convene a meeting of the ex officio members of the Board to—

(I) incorporate the Foundation and establish the general policies of the Foundation for carrying out the purposes of subsection (b), including the establishment of the bylaws of the Foundation; and

(II) appoint the members of the Board in accordance with subparagraph (C).

(ii) Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.

(E) The agreement of not less than three-fifths of the members of the ex officio members of the Board shall be required for the appointment of each member to the initial Board.

(F) No employee of the National Institutes of Health shall be appointed as a member of the Board.

(G) The Board may, through amendments to the bylaws of the Foundation, provide that the number of members of the Board shall be greater than the number specified in subparagraph (C).

(2) CHAIR.—

(A) The ex officio members of the Board under paragraph (1)(B) shall designate an individual to serve as the initial Chair of the Board.

(B)¹ Upon the termination of the term of service of the initial Chair of the Board, the appointed members of the Board shall elect a member of the Board to serve as the Chair of the Board.

(3) TERMS AND VACANCIES.—

(A) The term of office of each member of the Board appointed under paragraph (1)(C) shall be 5 years, except that the terms of offices for the initial appointed members

¹ Indentation so in law. See section 1701(4)(B)(iii) of Public Law 103-43 (107 Stat. 188).

of the Board shall expire as determined by the ex officio members and the Chair.

(B) Any vacancy in the membership of the Board shall be filled in the manner in which the original position was made and shall not affect the power of the remaining members to execute the duties of the Board.

(C) If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(D) A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

(5) MEETINGS AND QUORUM.—A majority of the members of the Board shall constitute a quorum for purposes of conducting the business of the Board.

(6) CERTAIN BYLAWS.—

(A) In establishing bylaws under this subsection, the Board shall ensure that the following are provided for:

(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

(ii) Policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation. Policies with respect to ethical standards shall ensure that officers, employees and agents of the Foundation (including members of the Board) avoid encumbrances that would result in a conflict of interest, including a financial conflict of interest or a divided allegiance. Such policies shall include requirements for the provision of information concerning any ownership or controlling interest in entities related to the activities of the Foundation by such officers, employees and agents and their spouses and relatives.

(iii) Policies for the conduct of the general operations of the Foundation.

(iv) Policies for writing, editing, printing, publishing, and vending of books and other materials.

(B) In establishing bylaws under this subsection, the Board shall ensure that such bylaws (and activities carried out under the bylaws) do not—

(i) reflect unfavorably upon the ability of the Foundation or the National Institutes of Health to carry out its responsibilities or official duties in a fair and objective manner; or

(ii) compromise, or appear to compromise, the integrity of any governmental agency or program, or any officer or employee involved in such program.

(f)¹ INCORPORATION.—The initial members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

(g) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of such section.

(h) EXECUTIVE DIRECTOR.—

(1) IN GENERAL.—The Foundation shall have an Executive Director who shall be appointed by the Board and shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

(2) COMPENSATION.—The rate of compensation of the Executive Director shall be fixed by the Board.

(i) POWERS.—In carrying out subsection (b), the Foundation may—

(1) operate under the direction of its Board;

(2) adopt, alter, and use a corporate seal, which shall be judicially noticed;

(3) provide for 1 or more officers, employees, and agents, as may be necessary, define their duties, and require surety bonds or make other provisions against losses occasioned by acts of such persons;

(4) hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees;

(5) with the consent of any executive department or independent agency, use the information, services, staff, and facilities of such in carrying out this section;

(6) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

(7) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this part;

(8) establish a process for the selection of candidates for positions under subsection (c);

(9) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

(10) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

(11) solicit² accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation;

(12) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director

¹There is no subsection (e). See section 1701(2) of Public Law 103-43 (107 Stat. 186).

²So in law. See section 1701(5)(F) of Public Law 103-43 (107 Stat. 189). There probably should be a comma after "solicit".

considers appropriate to conduct the activities of the Foundation;

(13) appoint other groups of advisors as may be determined necessary from time to time to carry out the functions of the Foundation;

(14) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation; and

(15) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this part.

(j) ADMINISTRATIVE CONTROL.—No participant in the program established under this part shall exercise any administrative control over any Federal employee.

(k) GENERAL PROVISIONS.—

(1) FOUNDATION INTEGRITY.—The members of the Board shall be accountable for the integrity of the operations of the Foundation and shall ensure such integrity through the development and enforcement of criteria and procedures relating to standards of conduct (including those developed under subsection (d)(2)(B)(i)(II)), financial disclosure statements, conflict of interest rules, recusal and waiver rules, audits and other matter determined appropriate by the Board.

(2) FINANCIAL CONFLICTS OF INTEREST.—Any individual who is an officer, employee, or member of the Board of the Foundation may not (in accordance with policies and requirements developed under subsection (d)(2)(B)(i)(II)) personally or substantially participate in the consideration or determination by the Foundation of any matter that would directly or predictably affect any financial interest of the individual or a relative (as such term is defined in section 109(16) of the Ethics in Government Act of 1978) of the individual, of any business organization or other entity, or of which the individual is an officer or employee, or is negotiating for employment, or in which the individual has any other financial interest.

(3) AUDITS; AVAILABILITY OF RECORDS.—The Foundation shall—

(A) provide for annual audits of the financial condition of the Foundation; and

(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

(4) REPORTS.—

(A) Not later than 5 months following the end of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation.

(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include

the source, and a description of, all gifts or grants to the Foundation of real or personal property, and the source and amount of all gifts or grants to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts or grants to the Foundation may be used.

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

(D) The Board shall annually hold a public meeting to summarize the activities of the Foundation and distribute written reports concerning such activities and the scientific results derived from such activities.

(5) SERVICE OF FEDERAL EMPLOYEES.—Federal employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its function, so long as the employees do not direct or control Foundation activities.

(6) RELATIONSHIP WITH EXISTING ENTITIES.—The Foundation may, pursuant to appropriate agreements, merge with, acquire, or use the resources of existing nonprofit private corporations with missions similar to the purposes of the Foundation, such as the Foundation for Advanced Education in the Sciences.

(7) INTELLECTUAL PROPERTY RIGHTS.—The Board shall adopt written standards with respect to the ownership of any intellectual property rights derived from the collaborative efforts of the Foundation prior to the commencement of such efforts.

(8) NATIONAL INSTITUTES OF HEALTH AMENDMENTS OF 1990.—The activities conducted in support of the National Institutes of Health Amendments of 1990 (Public Law 101-613), and the amendments made by such Act, shall not be nullified by the enactment of this section.

(9) LIMITATION OF ACTIVITIES.—The Foundation shall exist solely as an entity to work in collaboration with the research programs of the National Institutes of Health. The Foundation may not undertake activities (such as the operation of independent laboratories or competing for Federal research funds) that are independent of those of the National Institutes of Health research programs.

(10) TRANSFER OF FUNDS.—The Foundation may not transfer funds to the National Institutes of Health.

(1) DUTIES OF THE DIRECTOR.—

(1) APPLICABILITY OF CERTAIN STANDARDS TO NON-FEDERAL EMPLOYEES.—In the case of any individual who is not an employee of the Federal Government and who serves in association with the National Institutes of Health, with respect to financial assistance received from the Foundation, the Foundation may not provide the assistance of, or otherwise permit the work at the National Institutes of Health to begin until a memorandum of understanding between the individual and the

Director of the National Institutes of Health, or the designee of such Director, has been executed specifying that the individual shall be subject to such ethical and procedural standards of conduct relating to duties performed at the National Institutes of Health, as the Director of the National Institutes of Health determines is appropriate.

(2) SUPPORT SERVICES.—The Director of the National Institutes of Health may provide facilities, utilities and support services to the Foundation if it is determined by the Director to be advantageous to the research programs of the National Institutes of Health.

(m) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this part, there is authorized to be appropriated an aggregate \$200,000 for the fiscal years 1994 and 1995.

(2) LIMITATION REGARDING OTHER FUNDS.—Amounts appropriated under any provision of law other than paragraph (1) may not be expended to establish or operate the Foundation.

(n) REPORT ON ADEQUACY OF COMPLIANCE.—

(1) IN GENERAL.—With respect to the mission and function of the Foundation, the Comptroller General of the United States shall conduct an audit to determine—

(A) whether the Foundation is in compliance with the guidelines established under this section; and

(B) whether the procedures utilized under this section are adequate to prevent conflicts of interest involving the Foundation, the employees of the Foundation or members of the Board of the Foundation.

(2) REPORT.—Not later than 18 months after the date on which the Foundation is incorporated, the Comptroller General of the United States shall complete the audit required under paragraph (1) and prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report describing the findings made with respect to such audit.

TITLE V—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

PART A—ORGANIZATION AND GENERAL AUTHORITIES

SEC. 501. [290aa] SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.

(a) ESTABLISHMENT.—The Substance Abuse and Mental Health Services Administration (hereafter referred to in this title as the “Administration”) is an agency of the Service.

(b) AGENCIES.—The following entities are agencies of the Administration:

- (1) The Center for Substance Abuse Treatment.
- (2) The Center for Substance Abuse Prevention.
- (3) The Center for Mental Health Services.

(c) ADMINISTRATOR AND DEPUTY ADMINISTRATOR.—

(1) ADMINISTRATOR.—The Administration shall be headed by an Administrator (hereinafter in this title referred to as the “Administrator”) who shall be appointed by the President, by and with the advice and consent of the Senate.

(2) DEPUTY ADMINISTRATOR.—The Administrator, with the approval of the Secretary, may appoint a Deputy Administrator and may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the activities to be carried out through the Administration.

(d) AUTHORITIES.—The Secretary, acting through the Administrator, shall—

(1) supervise the functions of the agencies of the Administration in order to assure that the programs carried out through each such agency receive appropriate and equitable support and that there is cooperation among the agencies in the implementation of such programs;

(2) establish and implement, through the respective agencies, a comprehensive program to improve the provision of treatment and related services to individuals with respect to substance abuse and mental illness and to improve prevention services, promote mental health and protect the legal rights of individuals with mental illnesses and individuals who are substance abusers;

(3) carry out the administrative and financial management, policy development and planning, evaluation, knowledge dissemination, and public information functions that are required for the implementation of this title;

(4) assure that the Administration conduct and coordinate demonstration projects, evaluations, and service system assessments and other activities necessary to improve the availability and quality of treatment, prevention and related services;

(5) support activities that will improve the provision of treatment, prevention and related services, including the development of national mental health and substance abuse goals and model programs;

(6) in cooperation with the National Institutes of Health, the Centers for Disease Control and the Health Resources and Services Administration develop educational materials and intervention strategies to reduce the risks of HIV or tuberculosis among substance abusers and individuals with mental illness and to develop appropriate mental health services for individuals with such illnesses;

(7) coordinate Federal policy with respect to the provision of treatment services for substance abuse utilizing anti-addiction medications, including methadone;

(8) conduct programs, and assure the coordination of such programs with activities of the National Institutes of Health and the Agency for Health Care Policy Research¹, as appropriate, to evaluate the process, outcomes and community impact of treatment and prevention services and systems of care in order to identify the manner in which such services can most effectively be provided;

(9) collaborate with the Director of the National Institutes of Health in the development of a system by which the relevant research findings of the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Mental Health, and, as appropriate, the Agency for Health Care Policy Research¹ are disseminated to service providers in a manner designed to improve the delivery and effectiveness of treatment and prevention services;

(10) encourage public and private entities that provide health insurance to provide benefits for substance abuse and mental health services;

(11) promote the integration of substance abuse and mental health services into the mainstream of the health care delivery system of the United States;

(12) monitor compliance by hospitals and other facilities with the requirements of sections 542 and 543;

(13) with respect to grant programs authorized under this title, assure that—

(A) all grants that are awarded for the provision of services are subject to performance and outcome evaluations; and

(B) all grants that are awarded to entities other than States are awarded only after the State in which the entity intends to provide services—

(i) is notified of the pendency of the grant application; and

(ii) is afforded an opportunity to comment on the merits of the application;

¹So in law. See section 101(a) of Public Law 102-321 (106 Stat. 324). Probably should be "Agency for Health Care Policy and Research".

(14) assure that services provided with amounts appropriated under this title are provided bilingually, if appropriate;

(15) improve coordination among prevention programs, treatment facilities and nonhealth care systems such as employers, labor unions, and schools, and encourage the adoption of employee assistance programs and student assistance programs;

(16) maintain a clearinghouse for substance abuse and mental health information to assure the widespread dissemination of such information to States, political subdivisions, educational agencies and institutions, treatment providers, and the general public;

(17) in collaboration with the National Institute on Aging, and in consultation with the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism and the National Institute of Mental Health, as appropriate, promote and evaluate substance abuse services for older Americans in need of such services, and mental health services for older Americans who are seriously mentally ill; and

(18) promote the coordination of service programs conducted by other departments, agencies, organizations and individuals that are or may be related to the problems of individuals suffering from mental illness or substance abuse, including liaisons with the Social Security Administration, Health Care Financing Administration, and other programs of the Department, as well as liaisons with the Department of Education, Department of Justice, and other Federal Departments and offices, as appropriate.

(e) ASSOCIATE ADMINISTRATOR FOR ALCOHOL PREVENTION AND TREATMENT POLICY.—

(1) IN GENERAL.—There shall be in the Administration an Associate Administrator for Alcohol Prevention and Treatment Policy to whom the Administrator shall delegate the functions of promoting, monitoring, and evaluating service programs for the prevention and treatment of alcoholism and alcohol abuse within the Center for Substance Abuse Prevention, the Center for Substance Abuse Treatment, and the Center for Mental Health Services, and coordinating such programs among the Centers, and among the Centers and other public and private entities. The Associate Administrator also shall ensure that alcohol prevention, education, and policy strategies are integrated into all programs of the Centers that address substance abuse prevention, education, and policy, and that the Center for Substance Abuse Prevention addresses the Healthy People 2000 goals and the National Dietary Guidelines of the Department of Health and Human Services and the Department of Agriculture related to alcohol consumption.

(2) PLAN.—

(A) The Administrator, acting through the Associate Administrator for Alcohol Prevention and Treatment Policy, shall develop, and periodically review and as appropriate revise, a plan for programs and policies to treat and prevent alcoholism and alcohol abuse. The plan shall be developed (and reviewed and revised) in collaboration with

the Directors of the Centers of the Administration and in consultation with members of other Federal agencies and public and private entities.

(B) Not later than 1 year after the date of the enactment of the ADAMHA Reorganization Act, the Administrator shall submit to the Congress the first plan developed under subparagraph (A).

(3) REPORT.—

(A) Not less than once during each 2 years, the Administrator, acting through the Associate Administrator for Alcohol Prevention and Treatment Policy, shall prepare a report describing the alcoholism and alcohol abuse prevention and treatment programs undertaken by the Administration and its agencies, and the report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities.

(B) Each report under subparagraph (A) shall include a description of any revisions in the plan under paragraph (2) made during the preceding 2 years.

(C) Each report under subparagraph (A) shall be submitted to the Administrator for inclusion in the biennial report under subsection (k).

(f) ASSOCIATE ADMINISTRATOR FOR WOMEN'S SERVICES.—

(1) APPOINTMENT.—The Administrator, with the approval of the Secretary, shall appoint an Associate Administrator for Women's Services.

(2) DUTIES.—The Associate Administrator appointed under paragraph (1) shall—

(A) establish a committee to be known as the Coordinating Committee for Women's Services (hereafter in this subparagraph referred to as the "Coordinating Committee"), which shall be composed of the Directors of the agencies of the Administration (or the designees of the Directors);

(B) acting through the Coordinating Committee, with respect to women's substance abuse and mental health services—

(i) identify the need for such services, and make an estimate each fiscal year of the funds needed to adequately support the services;

(ii) identify needs regarding the coordination of services;

(iii) encourage the agencies of the Administration to support such services; and

(iv) assure that the unique needs of minority women, including Native American, Hispanic, African-American and Asian women, are recognized and addressed within the activities of the Administration; and

(C) establish an advisory committee to be known as the Advisory Committee for Women's Services, which shall be composed of not more than 10 individuals, a majority of whom shall be women, who are not officers or employees

of the Federal Government, to be appointed by the Administrator from among physicians, practitioners, treatment providers, and other health professionals, whose clinical practice, specialization, or professional expertise includes a significant focus on women's substance abuse and mental health conditions, that shall—

(i) advise the Associate Administrator on appropriate activities to be undertaken by the agencies of the Administration with respect to women's substance abuse and mental health services, including services which require a multidisciplinary approach;

(ii) collect and review data, including information provided by the Secretary (including the material referred to in paragraph (3)), and report biannually to the Administrator regarding the extent to which women are represented among senior personnel, and make recommendations regarding improvement in the participation of women in the workforce of the Administration; and

(iii) prepare, for inclusion in the biennial report required pursuant to subsection (k), a description of activities of the Committee, including findings made by the Committee regarding—

(I) the extent of expenditures made for women's substance abuse and mental health services by the agencies of the Administration; and

(II) the estimated level of funding needed for substance abuse and mental health services to meet the needs of women;

(D) improve the collection of data on women's health by—

(i) reviewing the current data at the Administration to determine its uniformity and applicability;

(ii) developing standards for all programs funded by the Administration so that data are, to the extent practicable, collected and reported using common reporting formats, linkages and definitions; and

(iii) reporting to the Administrator a plan for incorporating the standards developed under clause (ii) in all Administration programs and a plan to assure that the data so collected are accessible to health professionals, providers, researchers, and members of the public; and

(E) shall establish, maintain, and operate a program to provide information on women's substance abuse and mental health services.

(3) STUDY.—

(A) The Secretary, acting through the Assistant Secretary for Personnel, shall conduct a study to evaluate the extent to which women are represented among senior personnel at the Administration.

(B) Not later than 90 days after the date of the enactment of the ADAMHA Reorganization Act, the Assistant Secretary for Personnel shall provide the Advisory Com-

mittee for Women's Services with a study plan, including the methodology of the study and any sampling frames. Not later than 180 days after such date of enactment, the Assistant Secretary shall prepare and submit directly to the Advisory Committee a report concerning the results of the study conducted under subparagraph (A).

(C) The Secretary shall prepare and provide to the Advisory Committee for Women's Services any additional data as requested.

(4) DEFINITION.—For purposes of this subsection, the term “women's substance abuse and mental health conditions”, with respect to women of all age, ethnic, and racial groups, means all aspects of substance abuse and mental illness—

(A) unique to or more prevalent among women; or

(B) with respect to which there have been insufficient services involving women or insufficient data.

(g) SERVICES OF EXPERTS.—

(1) IN GENERAL.—The Administrator may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of service) the services of not more than 20 experts or consultants who have professional qualifications. Such experts and consultants shall be obtained for the Administration and for each of its agencies.

(2) COMPENSATION AND EXPENSES.—

(A) Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a)(1), 5724a(a)(3), and 5726(c) of title 5, United States Code.

(B) Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1), unless and until the expert or consultant agrees in writing to complete the entire period of assignment or one year, whichever is shorter, unless separated or reassigned for reasons beyond the control of the expert or consultant that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a debt of the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(h) PEER REVIEW GROUPS.—The Administrator shall, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates, establish such peer review groups and program advisory committees as are needed to carry out the requirements of this title and appoint and pay members of such groups, except that officers and employees of the United States shall not receive additional compensation for services as members of such groups. The Federal Advisory

Committee Act shall not apply to the duration of a peer review group appointed under this subsection.

(i) **VOLUNTARY SERVICES.**—The Administrator may accept voluntary and uncompensated services.

(j) **ADMINISTRATION.**—The Administrator shall ensure that programs and activities assigned under this title to the Administration are fully administered by the respective Centers to which such programs and activities are assigned.

(k) **REPORT CONCERNING ACTIVITIES AND PROGRESS.**—Not later than February 10, 1994, and once every 2 years thereafter, the Administrator shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, the report containing—

(1) a description of the activities carried out by the Administration;

(2) a description of any measurable progress made in improving the availability and quality of substance abuse and mental health services;

(3) a description of the mechanisms by which relevant research findings of the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute of Mental Health have been disseminated to service providers or otherwise utilized by the Administration to further the purposes of this title; and

(4) any report required in this title to be submitted to the Administrator for inclusion in the report under this subsection.

(l) **APPLICATIONS FOR GRANTS AND CONTRACTS.**—With respect to awards of grants, cooperative agreements, and contracts under this title, the Administrator, or the Director of the Center involved, as the case may be, may not make such an award unless—

(1) an application for the award is submitted to the official involved;

(2) with respect to carrying out the purpose for which the award is to be provided, the application provides assurances of compliance satisfactory to such official; and

(3) the application is otherwise in such form, is made in such manner, and contains such agreements, assurances, and information as the official determines to be necessary to carry out the purpose for which the award is to be provided.

(m) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of providing grants, cooperative agreements, and contracts under this section, there are authorized to be appropriated \$25,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

ADVISORY COUNCILS

SEC. 502. [290aa-1] (a) **APPOINTMENT.**—

(1) **IN GENERAL.**—The Secretary shall appoint an advisory council for—

(A) the Substance Abuse and Mental Health Services Administration;

(B) the Center for Substance Abuse Treatment;

(C) the Center for Substance Abuse Prevention; and

(D) the Center for Mental Health Services.

Each such advisory council shall advise, consult with, and make recommendations to the Secretary and the Administrator or Director of the Administration or Center for which the advisory council is established concerning matters relating to the activities carried out by and through the Administration or Center and the policies respecting such activities.

(2) FUNCTION AND ACTIVITIES.—An advisory council—

(A)(i) may on the basis of the materials provided by the organization respecting activities conducted at the organization, make recommendations to the Administrator or Director of the Administration or Center for which it was established respecting such activities;

(ii) shall review applications submitted for grants and cooperative agreements for activities for which advisory council approval is required under section 504(d)(2) and recommend for approval applications for projects that show promise of making valuable contributions to the Administration's mission; and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the organization;

(B) may collect, by correspondence or by personal investigation, information as to studies and services that are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the organization was established and with the approval of the Administrator or Director, whichever is appropriate, make such information available through appropriate publications for the benefit of public and private health entities and health professions personnel and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b) MEMBERSHIP.—

(1) IN GENERAL.—Each advisory council shall consist of nonvoting ex officio members and not more than 12 members to be appointed by the Secretary under paragraph (3).

(2) EX OFFICIO MEMBERS.—The ex officio members of an advisory council shall consist of—

(A) the Secretary;

(B) the Administrator;

(C) the Director of the Center for which the council is established;

(D) the Under Secretary for Health of the Department of Veterans Affairs;

(E) the Assistant Secretary for Defense for Health Affairs (or the designates of such officers); and

(F) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) APPOINTED MEMBERS.—Individuals shall be appointed to an advisory council under paragraph (1) as follows:

(A) Nine of the members shall be appointed by the Secretary from among the leading representatives of the health disciplines (including public health and behavioral and social sciences) relevant to the activities of the Administration or Center for which the advisory council is established.

(B) Three of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, public relations, law, health policy economics, or management.

(4) COMPENSATION.—Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The remaining members of an advisory council shall receive, for each day (including travel time) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent to the annual rate in effect for grade GS-18 of the General Schedule.

(c) TERMS OF OFFICE.—

(1) IN GENERAL.—The term of office of a member of an advisory council appointed under subsection (b) shall be 4 years, except that any member appointed to fill a vacancy for an unexpired term shall serve for the remainder of such term. The Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members not all expire in the same year. A member of an advisory council may serve after the expiration of such member's term until a successor has been appointed and taken office.

(2) REAPPOINTMENTS.—A member who has been appointed to an advisory council for a term of 4 years may not be reappointed to an advisory council during the 2-year period beginning on the date on which such 4-year term expired.

(3) TIME FOR APPOINTMENT.—If a vacancy occurs in an advisory council among the members under subsection (b), the Secretary shall make an appointment to fill such vacancy within 90 days from the date the vacancy occurs.

(d) CHAIR.—The Secretary shall select a member of an advisory council to serve as the chair of the council. The Secretary may so select an individual from among the appointed members, or may select the Administrator or the Director of the Center involved. The term of office of the chair shall be 2 years.

(e) MEETINGS.—An advisory council shall meet at the call of the chairperson or upon the request of the Administrator or Director of the Administration or Center for which the advisory council is established, but in no event less than 3 times during each fiscal year. The location of the meetings of each advisory council shall be subject to the approval of the Administrator or Director of Administration or Center for which the council was established.

(f) EXECUTIVE SECRETARY AND STAFF.—The Administrator or Director of the Administration or Center for which the advisory council is established shall designate a member of the staff of the Administration or Center for which the advisory council is established to serve as the Executive Secretary of the advisory council. The Administrator or Director shall make available to the advisory

council such staff, information, and other assistance as it may require to carry out its functions. The Administrator or Director shall provide orientation and training for new members of the advisory council to provide for their effective participation in the functions of the advisory council.

REPORTS ON ALCOHOLISM, ALCOHOL ABUSE, AND DRUG ABUSE

SEC. 503. [290aa-2] (a) The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

(1) containing current information on the health consequences of using alcoholic beverages,

(2) containing a description of current research findings made with respect to alcohol abuse and alcoholism, and

(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

(b) The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

(1) describing the health consequences and extent of drug abuse in the United States;

(2) describing current research findings made with respect to drug abuse, including current findings on the health effects of marihuana and the addictive property of tobacco; and

(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

PEER REVIEW

SEC. 504. [290aa-3] (a) IN GENERAL.—The Secretary, after consultation with the Directors of the Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, and the Center for Mental Health Services, shall require appropriate peer review of grants, cooperative agreements, and contracts to be administered through such Centers.

(b) MEMBERS.—The members of any peer review group established under regulations under subsection (a) shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group. Not more than one-fourth of the members of any peer review group established under such regulation shall be officers or employees of the United States.

(c) REQUIREMENTS.—Regulations promulgated pursuant to subsection (a)—

(1) shall require that the reviewing entity be provided a written description of the matter to be reviewed;

(2) shall require that the reviewing entity provide the advisory council of the Center involved with such description and the results of the review by the entity; and

(3) may specify the conditions under which limited exceptions may be granted to the limitations contained in the last sentence of subsection (b) and subsection (d).

(d) RECOMMENDATIONS.—

(1) IN GENERAL.—If the direct cost of a grant, cooperative agreement, or contract (described in subsection (a)) to be made

does not exceed \$50,000, the Secretary may make such grant, cooperative agreement, or contract only if such grant, cooperative agreement, or contract is recommended after peer review required by regulations under subsection (a).

(2) BY APPROPRIATE ADVISORY COUNCIL.—If the direct cost of a grant, cooperative agreement, or contract (described in subsection (a)) to be made exceeds \$50,000, the Secretary may make such grant, cooperative agreement, or contract only if such grant, cooperative agreement, or contract is recommended—

(A) after peer review required by regulations under subsection (a), and

(B) by the appropriate advisory council.

DATA COLLECTION

SEC. 505. [290aa-4] (a) The Secretary, acting through the Administrator, shall collect data each year on—

(1) the national incidence and prevalence of the various forms of mental illness and substance abuse; and

(2) the incidence and prevalence of such various forms in major metropolitan areas selected by the Administrator.

(b) With respect to the activities of the Administrator under subsection (a) relating to mental health, the Administrator shall ensure that such activities include, at a minimum, the collection of data on—

(1) the number and variety of public and nonprofit private treatment programs;

(2) the number and demographic characteristics of individuals receiving treatment through such programs;

(3) the type of care received by such individuals; and

(4) such other data as may be appropriate.

(c)(1) With respect to the activities of the Administrator under subsection (a) relating to substance abuse, the Administrator shall ensure that such activities include, at a minimum, the collection of data on—

(A) the number of individuals admitted to the emergency rooms of hospitals as a result of the abuse of alcohol or other drugs;

(B) the number of deaths occurring as a result of substance abuse, as indicated in reports by coroners;

(C) the number and variety of public and private nonprofit treatment programs, including the number and type of patient slots available;

(D) the number of individuals seeking treatment through such programs, the number and demographic characteristics of individuals receiving such treatment, the percentage of individuals who complete such programs, and, with respect to individuals receiving such treatment, the length of time between an individual's request for treatment and the commencement of treatment;

(E) the number of such individuals who return for treatment after the completion of a prior treatment in such programs and the method of treatment utilized during the prior treatment;

(F) the number of individuals receiving public assistance for such treatment programs;

(G) the costs of the different types of treatment modalities for drug and alcohol abuse and the aggregate relative costs of each such treatment modality provided within a State in each fiscal year;

(H) to the extent of available information, the number of individuals receiving treatment for alcohol or drug abuse who have private insurance coverage for the costs of such treatment;

(I) the extent of alcohol and drug abuse among high school students and among the general population; and

(J) the number of alcohol and drug abuse counselors and other substance abuse treatment personnel employed in public and private treatment facilities.

(2) Annual surveys shall be carried out in the collection of data under this subsection. Summaries and analyses of the data collected shall be made available to the public.

(d) After consultation with the States and with appropriate national organizations, the Administrator shall develop uniform criteria for the collection of data, using the best available technology, pursuant to this section.

GRANTS FOR THE BENEFIT OF HOMELESS INDIVIDUALS

SEC. 506. [290aa-5] (a) GRANTS FOR THE BENEFIT OF HOMELESS INDIVIDUALS.—The Secretary, acting through the Administrator, may make grants to, and enter into contracts and cooperative agreements with, community-based public and private non-profit entities for the purpose of developing and expanding mental health and substance abuse treatment services for homeless individuals. In carrying out this subsection, the Administrator shall consult with the Administrator of the Health Resources and Services Administration, the Directors of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health, and the Commissioner of the Administration for Children, Youth and Families.

(b) PREFERENCE.—In awarding grants under subsection (a), the Secretary shall give preference to entities that provide integrated primary health care, substance abuse and mental health services to homeless individuals.

(c) SERVICES FOR CERTAIN INDIVIDUALS.—In making awards under subsection (a), the Secretary may not prohibit the provision of services under such subsection to homeless individuals who have a primary diagnosis of substance abuse and are not suffering from mental illness.

(d) TERM OF GRANT.—No entity may receive grants under subsection (a) for more than 5 years although such grants may be renewed.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, \$50,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

PART B—CENTERS AND PROGRAMS

Subpart 1—Center for Substance Abuse Treatment

CENTER FOR SUBSTANCE ABUSE TREATMENT

SEC. 507. [290bb] (a) ESTABLISHMENT.—There is established in the Administration a Center for Substance Abuse Treatment (hereafter in this section referred to as the "Center"). The Center shall be headed by a Director (hereafter in this section referred to as the "Director") appointed by the Secretary from among individuals with extensive experience or academic qualifications in the treatment of substance abuse or in the evaluation of substance abuse treatment systems.

(b) DUTIES.—The Director of the Center shall—

(1) administer the substance abuse treatment block grant program authorized in section 1921;

(2) collaborate with the Director of the Center for Substance Abuse Prevention in order to provide outreach services to identify individuals in need of treatment services, with emphasis on the provision of such services to pregnant and postpartum women and their infants and to individuals who abuse drugs intravenously;

(3) collaborate with the Director of the National Institute on Drug Abuse, with the Director of the National Institute on Alcohol Abuse and Alcoholism, and with the States to promote the study, dissemination, and implementation of research findings that will improve the delivery and effectiveness of treatment services;

(4) collaborate with the Administrator of the Health Resources and Services Administration and the Administrator of the Health Care Financing Administration to promote the increased integration into the mainstream of the health care system of the United States of programs for providing treatment services;

(5) evaluate plans submitted by the States pursuant to section 1932(a)(6) in order to determine whether the plans adequately provide for the availability, allocation, and effectiveness of treatment services, and monitor the use of revolving loan funds pursuant to section 1925;

(6) sponsor regional workshops on improving the quality and availability of treatment services;

(7) provide technical assistance to public and nonprofit private entities that provide treatment services, including technical assistance with respect to the process of submitting to the Director applications for any program of grants or contracts carried out by the Director;

(8) encourage the States to expand the availability (relative to fiscal year 1992) of programs providing treatment services through self-run, self-supported recovery based on the programs of housing operated pursuant to section 1925;

(9) carry out activities to educate individuals on the need for establishing treatment facilities within their communities;

(10) encourage public and private entities that provide health insurance to provide benefits for outpatient treatment services and other nonhospital-based treatment services;

(11) evaluate treatment programs to determine the quality and appropriateness of various forms of treatment, including the effect of living in housing provided by programs established under section 1925, which shall be carried out through grants, contracts, or cooperative agreements provided to public or non-profit private entities; and

(12) in carrying out paragraph (11), assess the quality, appropriateness, and costs of various treatment forms for specific patient groups.

(c) GRANTS AND CONTRACTS.—In carrying out the duties established in subsection (b), the Director may make grants to and enter into contracts and cooperative agreements with public and non-profit private entities.

RESIDENTIAL TREATMENT PROGRAMS FOR PREGNANT AND POSTPARTUM WOMEN

SEC. 508. [290bb-1] (a) IN GENERAL.—The Director of the Center for Substance Abuse Treatment shall provide awards of grants, cooperative agreement, or contracts to public and nonprofit private entities for the purpose of providing to pregnant and postpartum women treatment for substance abuse through programs in which, during the course of receiving treatment—

(1) the women reside in facilities provided by the programs;

(2) the minor children of the women reside with the women in such facilities, if the women so request; and

(3) the services described in subsection (d) are available to or on behalf of the women.

(b) AVAILABILITY OF SERVICES FOR EACH PARTICIPANT.—A funding agreement for an award under subsection (a) for an applicant is that, in the program operated pursuant to such subsection—

(1) treatment services and each supplemental service will be available through the applicant, either directly or through agreements with other public or nonprofit private entities; and

(2) the services will be made available to each woman admitted to the program.

(c) INDIVIDUALIZED PLAN OF SERVICES.—A funding agreement for an award under subsection (a) for an applicant is that—

(1) in providing authorized services for an eligible woman pursuant to such subsection, the applicant will, in consultation with the women, prepare an individualized plan for the provision to the woman of the services; and

(2) treatment services under the plan will include—

(A) individual, group, and family counseling, as appropriate, regarding substance abuse; and

(B) follow-up services to assist the woman in preventing a relapse into such abuse.

(d) REQUIRED SUPPLEMENTAL SERVICES.—In the case of an eligible woman, the services referred to in subsection (a)(3) are as follows:

- (1) Prenatal and postpartum health care.
 - (2) Referrals for necessary hospital services.
 - (3) For the infants and children of the woman—
 - (A) pediatric health care, including treatment for any perinatal effects of maternal substance abuse and including screenings regarding the physical and mental development of the infants and children;
 - (B) counseling and other mental health services, in the case of children; and
 - (C) comprehensive social services.
 - (4) Providing supervision of children during periods in which the woman is engaged in therapy or in other necessary health or rehabilitative activities.
 - (5) Training in parenting.
 - (6) Counseling on the human immunodeficiency virus and on acquired immune deficiency syndrome.
 - (7) Counseling on domestic violence and sexual abuse.
 - (8) Counseling on obtaining employment, including the importance of graduating from a secondary school.
 - (9) Reasonable efforts to preserve and support the family units of the women, including promoting the appropriate involvement of parents and others, and counseling the children of the women.
 - (10) Planning for and counseling to assist reentry into society, both before and after discharge, including referrals to any public or nonprofit private entities in the community involved that provide services appropriate for the women and the children of the women.
 - (11) Case management services, including—
 - (A) assessing the extent to which authorized services are appropriate for the women and their children;
 - (B) in the case of the services that are appropriate, ensuring that the services are provided in a coordinated manner; and
 - (C) assistance in establishing eligibility for assistance under Federal, State, and local programs providing health services, mental health services, housing services, employment services, educational services, or social services.
- (e) MINIMUM QUALIFICATIONS FOR RECEIPT OF AWARD.—
- (1) CERTIFICATION BY RELEVANT STATE AGENCY.—With respect to the principal agency of the State involved that administers programs relating to substance abuse, the Director may make an award under subsection (a) to an applicant only if the agency has certified to the Director that—
 - (A) the applicant has the capacity to carry out a program described in subsection (a);
 - (B) the plans of the applicant for such a program are consistent with the policies of such agency regarding the treatment of substance abuse; and
 - (C) the applicant, or any entity through which the applicant will provide authorized services, meets all applicable State licensure or certification requirements regarding the provision of the services involved.
 - (2) STATUS AS MEDICAID PROVIDER.—

(A) Subject to subparagraphs (B) and (C), the Director may make an award under subsection (a) only if, in the case of any authorized service that is available pursuant to the State plan approved under title XIX of the Social Security Act for the State involved—

(i) the applicant for the award will provide the service directly, and the applicant has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the applicant will enter into an agreement with a public or nonprofit private entity under which the entity will provide the service, and the entity has entered into such a participation agreement plan and is qualified to receive such payments.

(B)(i) In the case of an entity making an agreement pursuant to subparagraph (A)(ii) regarding the provision of services, the requirement established in such subparagraph regarding a participation agreement shall be waived by the Director if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits plan.

(ii) A determination by the Director of whether an entity referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the entity accepts voluntary donations regarding the provision of services to the public.

(C) With respect to any authorized service that is available pursuant to the State plan described in subparagraph (A), the requirements established in such subparagraph shall not apply to the provision of any such service by an institution for mental diseases to an individual who has attained 21 years of age and who has not attained 65 years of age. For purposes of the preceding sentence, the term "institution for mental diseases" has the meaning given such term in section 1905(i) of the Social Security Act.

(f) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—With respect to the costs of the program to be carried out by an applicant pursuant to subsection (a), a funding agreement for an award under such subsection is that the applicant will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that—

(A) for the first fiscal year for which the applicant receives payments under an award under such subsection, is not less than \$1 for each \$9 of Federal funds provided in the award;

(B) for any second such fiscal year, is not less than \$1 for each \$9 of Federal funds provided in the award; and

(C) for any subsequent such fiscal year, is not less than \$1 for each \$3 of Federal funds provided in the award.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(g) OUTREACH.—A funding agreement for an award under subsection (a) for an applicant is that the applicant will provide outreach services in the community involved to identify women who are engaging in substance abuse and to encourage the women to undergo treatment for such abuse.

(h) ACCESSIBILITY OF PROGRAM; CULTURAL CONTEXT OF SERVICES.—A funding agreement for an award under subsection (a) for an applicant is that—

(1) the program operated pursuant to such subsection will be operated at a location that is accessible to low-income pregnant and postpartum women; and

(2) authorized services will be provided in the language and the cultural context that is most appropriate.

(i) CONTINUING EDUCATION.—A funding agreement for an award under subsection (a) is that the applicant involved will provide for continuing education in treatment services for the individuals who will provide treatment in the program to be operated by the applicant pursuant to such subsection.

(j) IMPOSITION OF CHARGES.—A funding agreement for an award under subsection (a) for an applicant is that, if a charge is imposed for the provision of authorized services to on behalf of an eligible woman, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the woman involved; and

(3) will not be imposed on any such woman with an income of less than 185 percent of the official poverty line, as established by the Director of the Office for Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(k) REPORTS TO DIRECTOR.—A funding agreement for an award under subsection (a) is that the applicant involved will submit to the Director a report—

(1) describing the utilization and costs of services provided under the award;

(2) specifying the number of women served, the number of infants served, and the type and costs of services provided; and

(3) providing such other information as the Director determines to be appropriate.

(l) REQUIREMENT OF APPLICATION.—The Director may make an award under subsection (a) only if an application for the award is submitted to the Director containing such agreements, and the application is in such form, is made in such manner, and contains such other agreements and such assurances and information as the Director determines to be necessary to carry out this section.

(m) **EQUITABLE ALLOCATION OF AWARDS.**—In making awards under subsection (a), the Director shall ensure that the awards are equitably allocated among the principal geographic regions of the United States, subject to the availability of qualified applicants for the awards.

(n) **DURATION OF AWARD.**—The period during which payments are made to an entity from an award under subsection (a) may not exceed 5 years. The provision of such payments shall be subject to annual approval by the Director of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments. This subsection may not be construed to establish a limitation on the number of awards under such subsection that may be made to an entity.

(o) **EVALUATIONS; DISSEMINATION OF FINDINGS.**—The Director shall, directly or through contract, provide for the conduct of evaluations of programs carried out pursuant to subsection (a). The Director shall disseminate to the States the findings made as a result of the evaluations.

(p) **REPORTS TO CONGRESS.**—Not later than October 1, 1994, the Director shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing programs carried out pursuant to this section. Every 2 years thereafter, the Director shall prepare a report describing such programs carried out during the preceding 2 years, and shall submit the report to the Administrator for inclusion in the biennial report under section 501(k). Each report under this subsection shall include a summary of any evaluations conducted under subsection (m) during the period with respect to which the report is prepared.

(q) **DEFINITIONS.**—For purposes of this section:

(1) The term “authorized services” means treatment services and supplemental services.

(2) The term “eligible woman” means a woman who has been admitted to a program operated pursuant to subsection (a).

(3) The term “funding agreement under subsection (a)”, with respect to an award under subsection (a), means that the Director may make the award only if the applicant makes the agreement involved.

(4) The term “treatment services” means treatment for substance abuse, including the counseling and services described in subsection (c)(2).

(5) The term “supplemental services” means the services described in subsection (d).

(r) **AUTHORIZATION OF APPROPRIATIONS.**—

(1) **IN GENERAL.**—For the purpose of carrying out this section and section 509, there are authorized to be appropriated \$100,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(2) **TRANSFER.**—For the purpose described in paragraph (1), in addition to the amounts authorized in such paragraph to be appropriated for a fiscal year, there is authorized to be appropriated for the fiscal year from the special forfeiture fund

of the Director of the Office of National Drug Control Policy such sums as may be necessary.

(3) **RULE OF CONSTRUCTION.**—The amounts authorized in this subsection to be appropriated are in addition to any other amounts that are authorized to be appropriated and are available for the purpose described in paragraph (1).

OUTPATIENT TREATMENT PROGRAMS FOR PREGNANT AND POSTPARTUM WOMEN

SEC. 509. [290bb-2] (a) **GRANTS.**—The Secretary, acting through the Director of the Treatment Center, shall make grants to establish projects for the outpatient treatment of substance abuse among pregnant and postpartum women, and in the case of conditions arising in the infants of such women as a result of such abuse by the women, the outpatient treatment of the infants for such conditions.

(b) **PREVENTION.**—Entities receiving grants under this section shall engage in activities to prevent substance abuse among pregnant and postpartum women.

(c) **EVALUATION.**—The Secretary shall evaluate projects carried out under subsection (a) and shall disseminate to appropriate public and private entities information on effective projects.

DEMONSTRATION PROJECTS OF NATIONAL SIGNIFICANCE

SEC. 510. [290bb-3] (a) **GRANTS FOR TREATMENT IMPROVEMENT.**—The Director of the Center for Substance Abuse Treatment shall provide grants to public and nonprofit private entities for the purpose of establishing demonstration projects that will improve the provision of treatment services for substance abuse.

(b) **NATURE OF PROJECTS.**—Grants under subsection (a) shall be awarded to—

(1) projects that provide treatment to adolescents, female addicts and their children, racial and ethnic minorities, or individuals in rural areas, with preference given to such projects that provide treatment for substance abuse to women with dependent children, which treatment is provided in settings in which both primary health services for the women and pediatric care are available;

(2) projects that provide treatment in exchange for public service;

(3) projects that provide treatment services and which are operated by public and nonprofit private entities receiving grants under section 329, 330, 340, 340A, or other public or nonprofit private entities that provide primary health services;

(4) “treatment campus” projects that—

(A) serve a significant number of individuals simultaneously;

(B) provide residential, non-community based drug treatment;

(C) provide patients with ancillary social services and referrals to community-based aftercare; and

(D) provide services on a voluntary basis;

(5) projects in large metropolitan areas to identify individuals in need of treatment services and to improve the availability and delivery of such services in the areas;

(6) in the case of drug abusers who are at risk of HIV infection, projects to conduct outreach activities to the individuals regarding the prevention of exposure to and the transmission of the human immunodeficiency virus, and to encourage the individuals to seek treatment for such abuse; and

(7) projects to determine the long-term efficacy of the projects described in this section and to disseminate to appropriate public and private entities information on the projects that have been effective.

(c) PREFERENCES IN MAKING GRANTS.—In awarding grants under subsection (a), the Director of the Treatment Center shall give preference to projects that—

(1) demonstrate a comprehensive approach to the problems associated with substance abuse and provide evidence of broad community involvement and support; or

(2) initiate and expand programs for the provision of treatment services (including renovation of facilities, but not construction) in localities in which, and among populations for which, there is a public health crisis as a result of the inadequate availability of such services and a substantial rate of substance abuse.

(d) DURATION OF GRANTS.—The period during which payments are made under a grant under subsection (a) may not exceed 5 years.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated \$175,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994. The amounts so authorized are in addition to any other amounts that are authorized to be appropriated and available for such purpose.

(2) ALLOCATION.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Director of the Treatment Center shall reserve not less than 5 percent for carrying out projects described in subsections (b)(2) and (b)(3).

GRANTS FOR SUBSTANCE ABUSE TREATMENT IN STATE AND LOCAL CRIMINAL JUSTICE SYSTEMS

SEC. 511. [290bb-4] (a) IN GENERAL.—The Director of the Center for Substance Abuse Treatment shall provide grants to public and nonprofit private entities that provide treatment for substance abuse to individuals under criminal justice supervision.

(b) ELIGIBILITY.—In awarding grants under subsection (a), the Director shall ensure that the grants are reasonably distributed among—

(1) projects that provide treatment services to individuals who are incarcerated in prisons, jails, or community correctional settings; and

(2) projects that provide treatment services to individuals who are not incarcerated, but who are under criminal justice

supervision because of their status as pretrial releasees, post-trial releasees, probationers, parolees, or supervised releasees.

(c) **PRIORITY.**—In awarding grants under subsection (a), the Director shall give priority to programs commensurate with the extent to which such programs provide, directly or in conjunction with other public or private nonprofit entities, one or more of the following—

(1) a continuum of offender management services as individuals enter, proceed through, and leave the criminal justice system, including identification and assessment, substance abuse treatment, pre-release counseling and pre-release referrals with respect to housing, employment and treatment;

(2) comprehensive treatment services for juvenile offenders;

(3) comprehensive treatment services for female offenders, including related services such as violence counseling, parenting and child development classes, and perinatal care;

(4) outreach services to identify individuals under criminal justice supervision who would benefit from substance abuse treatment and to encourage such individuals to seek treatment; or

(5) treatment services that function as an alternative to incarceration for appropriate categories of offenders or that otherwise enable individuals to remain under criminal justice supervision in the least restrictive setting consistent with public safety.

(d) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there are authorized to be appropriated \$50,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

TRAINING IN PROVISION OF TREATMENT SERVICES

SEC. 512. [290bb-5] (a) IN GENERAL.—The Director of the Center for Substance Abuse Treatment shall develop programs to increase the number of substance abuse treatment professionals and the number of health professionals providing treatment services through the awarding of grants to appropriate public and nonprofit private entities, including agencies of State and local governments, hospitals, schools of medicine, schools of osteopathic medicine, schools of nursing, schools of social work, and graduate programs in marriage and family therapy.

(b) **PRIORITY.**—In awarding grants under subsection (a), the Director shall give priority to projects that train full-time substance abuse treatment professionals and projects that will receive financial support from public entities for carrying out the projects.

(c) **HEALTH PROFESSIONS EDUCATION.**—In awarding grants under subsection (a), the Director may make grants—

(1) to train individuals in the diagnosis and treatment of alcohol abuse and other drug abuse; and

(2) to develop appropriate curricula and materials for the training described in paragraph (1).

(d) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there are authorized to be appropriated

\$30,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

ACTION BY NATIONAL INSTITUTE ON DRUG ABUSE AND STATES
CONCERNING MILITARY FACILITIES

SEC. 513. [290bb-6] (a) CENTER FOR SUBSTANCE ABUSE TREATMENT.—The Director of the Center for Substance Abuse Treatment shall—

(1) coordinate with the agencies represented on the Commission on Alternative Utilization of Military Facilities the utilization of military facilities or parts thereof, as identified by such Commission, established under the National Defense Authorization Act of 1989, that could be utilized or renovated to house nonviolent persons for drug treatment purposes;

(2) notify State agencies responsible for the oversight of drug abuse treatment entities and programs of the availability of space at the installations identified in paragraph (1); and

(3) assist State agencies responsible for the oversight of drug abuse treatment entities and programs in developing methods for adapting the installations described in paragraph (1) into residential treatment centers.

(b) STATES.—With regard to military facilities or parts thereof, as identified by the Commission on Alternative Utilization of Military Facilities established under section 3042 of the Comprehensive Alcohol Abuse, Drug Abuse, and Mental Health Amendments Act of 1988, that could be utilized or renovated to house nonviolent persons for drug treatment purposes, State agencies responsible for the oversight of drug abuse treatment entities and programs shall—

(1) establish eligibility criteria for the treatment of individuals at such facilities;

(2) select treatment providers to provide drug abuse treatment at such facilities;

(3) provide assistance to treatment providers selected under paragraph (2) to assist such providers in securing financing to fund the cost of the programs at such facilities; and

(4) establish, regulate, and coordinate with the military official in charge of the facility, work programs for individuals receiving treatment at such facilities.

(c) RESERVATION OF SPACE.—Prior to notifying States of the availability of space at military facilities under subsection (a)(2), the Director may reserve space at such facilities to conduct research or demonstration projects.

Subpart 2—Center for Substance Abuse Prevention

OFFICE FOR SUBSTANCE ABUSE PREVENTION

SEC. 515. [290bb-21] (a) There is established in the Administration an Office for Substance Abuse Prevention (hereafter referred to in this part as the "Prevention Center").

(b) The Director of the Prevention Center shall—

(1) sponsor regional workshops on the prevention of drug and alcohol abuse;

(2) coordinate the findings of research sponsored by agencies of the Service on the prevention of drug and alcohol abuse;

(3) develop effective drug and alcohol abuse prevention literature (including literature on the adverse effects of cocaine free base (known as crack));

(4) in cooperation with the Secretary of Education, assure the widespread dissemination of prevention materials among States, political subdivisions, and school systems;

(5) support clinical training programs for substance abuse counselors and other health professionals involved in drug abuse education, prevention;¹

(6) in cooperation with the Director of the Centers for Disease Control², develop educational materials to reduce the risks of acquired immune deficiency syndrome among intravenous drug abusers;

(7) conduct training, technical assistance, data collection, and evaluation activities of programs supported under the Drug Free Schools and Communities Act of 1986;

(8) support the development of model, innovative, community-based programs to discourage alcohol and drug abuse among young people;

(9) prepare for distribution documentary films and public service announcements for television and radio to educate the public concerning the dangers to health resulting from the consumption of alcohol and drugs and, to the extent feasible, use appropriate private organizations and business concerns in the preparation of such announcements; and

(10) develop and support innovative demonstration programs designed to identify and deter the improper use or abuse of anabolic steroids by students, especially students in secondary schools.

(c) The Director may make grants and enter into contracts and cooperative agreements in carrying out subsection (b).

(d) The Director of the Prevention Center shall establish a national data base providing information on programs for the prevention of substance abuse. The data base shall contain information appropriate for use by public entities and information appropriate for use by nonprofit private entities.

COMMUNITY PROGRAMS

SEC. 516. [290bb-22] (a) IN GENERAL.—The Secretary, acting through the Director of the Prevention Center, shall—

(1) provide assistance to communities to develop comprehensive long-term strategies for the prevention of substance abuse; and

(2) evaluate the success of different community approaches toward the prevention of such abuse.

(b) STRATEGIES FOR REDUCING USE.—The Director of the Prevention Center shall ensure that strategies developed under sub-

¹ So in law. See section 113(c)(1) of Public Law 102-321 (106 Stat. 345).

² So in law. See section 113(b) of Public Law 102-321 (106 Stat. 345). Probably should be "Centers for Disease Control and Prevention". Section 515 formerly was section 508, and after such redesignation, section 312(d)(10) of Public Law 102-531 (106 Stat. 3505) purported to amend "section 508(b)(6)" with respect to adding "and Prevention".

section (a)(1) include strategies for reducing the use of alcoholic beverages and tobacco products by individuals to whom it is unlawful to sell or distribute such beverages or products.

(c) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out subsection (a), there are authorized to be appropriated \$120,000,000 for fiscal year 1993, such sums as may be necessary for fiscal year 1994.

PREVENTION, TREATMENT, AND REHABILITATION MODEL PROJECTS
FOR HIGH RISK YOUTH

SEC. 517. [290bb–23] (a) The Secretary, through the Director of the Prevention Center, shall make grants to public and non-profit private entities for projects to demonstrate effective models for the prevention, treatment, and rehabilitation of drug abuse and alcohol abuse among high risk youth.

(b)(1) In making grants for drug abuse and alcohol abuse prevention projects under this section, the Secretary shall give priority to applications for projects directed at children of substance abusers, latchkey children, children at risk of abuse or neglect, preschool children eligible for services under the Head Start Act, children at risk of dropping out of school, children at risk of becoming adolescent parents, and children who do not attend school and who are at risk of being unemployed.

(2) In making grants for drug abuse and alcohol abuse treatment and rehabilitation projects under this section, the Secretary shall give priority to projects which address the relationship between drug abuse or alcohol abuse and physical child abuse, sexual child abuse, emotional child abuse, dropping out of school, unemployment, delinquency, pregnancy, violence, suicide, or mental health problems.

(3) In making grants under this section, the Secretary shall give priority to applications from community based organizations for projects to develop innovative models with multiple, coordinated services for the prevention or for the treatment and rehabilitation of drug abuse or alcohol abuse by high risk youth.

(4) In making grants under this section, the Secretary shall give priority to applications for projects to demonstrate effective models with multiple, coordinated services which may be replicated and which are for the prevention or for the treatment and rehabilitation of drug abuse or alcohol abuse by high risk youth.

(5) In making grants under this section, the Secretary shall give priority to applications that employ research designs adequate for evaluating the effectiveness of the program.

(c) The Secretary shall ensure that projects under subsection (a) include strategies for reducing the use of alcoholic beverages and tobacco products by individuals to whom it is unlawful to sell or distribute such beverages or products.

(d) To the extent feasible, the Secretary shall make grants under this section in all regions of the United States, and shall ensure the distribution of grants under this section among urban and rural areas.

(e) In order to receive a grant for a project under this section for a fiscal year, a public or nonprofit private entity shall submit

an application to the Secretary, acting through the Office. The Secretary may provide to the Governor of the State the opportunity to review and comment on such application. Such application shall be in such form, shall contain such information, and shall be submitted at such time as the Secretary may by regulation prescribe.

(f) The Director of the Office shall evaluate projects conducted with grants under this section.

(g) For purposes of this section, the term "high risk youth" means an individual who has not attained the age of 21 years, who is at high risk of becoming, or who has become, a drug abuser or an alcohol abuser, and who—

- (1) is identified as a child of a substance abuser;
- (2) is a victim of physical, sexual, or psychological abuse;
- (3) has dropped out of school;
- (4) has become pregnant;
- (5) is economically disadvantaged;
- (6) has committed a violent or delinquent act;
- (7) has experienced mental health problems;
- (8) has attempted suicide;
- (9) has experienced long-term physical pain due to injury;

or

- (10) has experienced chronic failure in school.

(h) For the purpose of carrying out this section, there are authorized to be appropriated \$70,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

SEC. 518. [290bb-24] EMPLOYEE ASSISTANCE PROGRAMS.

(a) IN GENERAL.—The Director of the Prevention Center may make grants to public and nonprofit private entities for the purpose of assisting business organizations in establishing employee assistance programs to provide appropriate services for employees of the organizations regarding substance abuse, including education and prevention services and referrals for treatment.

(b) CERTAIN REQUIREMENTS.—A business organization may not be assisted under subsection (a) if the organization has an employee assistance program in operation. The organization may receive such assistance only if the organization lacks the financial resources for operating such a program.

(c) SPECIAL CONSIDERATION FOR CERTAIN SMALL BUSINESSES.—In making grants under subsection (a), the Director of the Prevention Office shall give special consideration to business organizations with 50 or fewer employers.

(d) CONSULTATION AND TECHNICAL ASSISTANCE.—In the case of small businesses being assisted under subsection (a), the Secretary shall consult with the entities and organizations involved and provide technical assistance and training with respect to establishing and operating employee assistance programs in accordance with this subtitle.¹ Such assistance shall include technical assistance in establishing workplace substance abuse programs.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated

¹ So in original. See section 171 of Public Law 102-321 (106 Stat. 377). This title is not organized into subtitles. Probably should be "section".

\$3,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

Subpart 3—Center for Mental Health Services

CENTER FOR MENTAL HEALTH SERVICES

SEC. 520. [290bb-31] (a) ESTABLISHMENT.—There is established in the Administration a Center for Mental Health Services (hereafter in this section referred to as the “Center”). The Center shall be headed by a Director (hereafter in this section referred to as the “Director”) appointed by the Secretary from among individuals with extensive experience or academic qualifications in the provision of mental health services or in the evaluation of mental health service systems.

(b) DUTIES.—The Director of the Center shall—

(1) design national goals and establish national priorities for—

(A) the prevention of mental illness; and

(B) the promotion of mental health;

(2) encourage and assist local entities and State agencies to achieve the goals and priorities described in paragraph (1);

(3) develop and coordinate Federal prevention policies and programs and to assure increased focus on the prevention of mental illness and the promotion of mental health;

(4) develop improved methods of treating individuals with mental health problems and improved methods of assisting the families of such individuals;

(5) administer the mental health services block grant program authorized in section 1911;

(6) promote policies and programs at Federal, State, and local levels and in the private sector that foster independence and protect the legal rights of persons with mental illness, including carrying out the provisions of the Protection and Advocacy of Mentally Ill Individuals Act;

(7) carry out the programs authorized under sections 520A and 521, including the Community Support Program and the Child and Adolescent Service System Programs;

(8) carry out responsibilities for the Human Resource Development program, and programs of clinical training for professional and paraprofessional personnel pursuant to section 303;

(9) conduct services-related assessments, including evaluations of the organization and financing of care, self-help and consumer-run programs, mental health economics, mental health service systems, rural mental health, and improve the capacity of State to conduct evaluations of publicly funded mental health programs;

(10) establish a clearinghouse for mental health information to assure the widespread dissemination of such information to States, political subdivisions, educational agencies and institutions, treatment and prevention service providers, and the general public, including information concerning the practical application of research supported by the National Insti-

tute of Mental Health that is applicable to improving the delivery of services;

(11) provide technical assistance to public and private entities that are providers of mental health services;

(12) monitor and enforce obligations incurred by community mental health centers pursuant to the Community Mental Health Centers Act (as in effect prior to the repeal of such Act on August 13, 1981, by section 902(e)(2)(B) of Public Law 97-35 (95 Stat. 560));

(13) conduct surveys with respect to mental health, such as the National Reporting Program; and

(14) assist States in improving their mental health data collection.

(c) GRANTS AND CONTRACTS.—In carrying out the duties established in subsection (b), the Director may make grants to and enter into contracts and cooperative agreements with public and non-profit private entities.

ESTABLISHMENT OF GRANT PROGRAMS FOR DEMONSTRATION PROJECTS

SEC. 520A. ¹ [290bb-32] (a) SERIOUSLY MENTALLY ILL INDIVIDUALS, AND CHILDREN AND ADOLESCENTS WITH SERIOUS EMOTIONAL AND MENTAL DISTURBANCES.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Center for Mental Health Services, may make grants to States, political subdivisions of States, and nonprofit private agencies for—

(A) mental health services demonstration projects for the planning, coordination and improvement of community services (including outreach and consumer-run self-help services) for seriously mentally ill individuals and their families, seriously emotionally and mentally disturbed children and youth and their families, and seriously mentally ill homeless and elderly individuals;

(B) demonstration projects for the prevention of youth suicide;

(C) demonstration projects for the improvement of the recognition, assessment, treatment and clinical management of depressive disorders;

(D) demonstration projects for programs to prevent the occurrence of sex offenses, and for the provision of treatment and psychological assistance to the victims of sex offenses; and

(E) demonstration projects for programs to provide mental health services to victims of family violence.

(2) MENTAL HEALTH SERVICES.—Mental health services provided under paragraph (1)(A) should encompass a range of delivery systems designed to permit individuals to receive

¹Section 612 of Public Law 100-77 (42 U.S.C. 290bb-32 note) provided an authorization of appropriations for carrying out "section 520" in addition to the authorization provided by subsection (e) of such section. (Section 520 was redesignated as section 520A by section 116(a) of Public Law 102-321 (106 Stat. 348).) Appropriations under the additional authorization provided by such section 612 were available only for the provision of community-based mental health services to homeless individuals who are chronically mentally ill. The additional authorization was provided with respect to the fiscal years 1991 through 1993.

treatment in the most therapeutically appropriate, least restrictive setting. Grants shall be awarded under such paragraph for—

(A) research demonstration programs concerning such services; and

(B) systems improvements to assist States and local entities to develop appropriate comprehensive mental health systems for adults with serious long-term mental illness and children and adolescents with serious emotional and mental disturbance.

(b) INDIVIDUALS AT RISK OF MENTAL ILLNESS.—

(1) The Secretary, acting through the Director, may make grants to States, political subdivisions of States, and private nonprofit agencies for prevention services demonstration projects for the provision of prevention services for individuals who, in the determination of the Secretary, are at risk of developing mental illness.

(2) Demonstration projects under paragraph (1) may include—

(A) prevention services for populations at risk of developing mental illness, particularly displaced workers, young children, and adolescents;

(B) the development and dissemination of education materials;

(C) the sponsoring of local, regional, or national workshops or conferences;

(D) the conducting of training programs with respect to the provision of mental health services to individuals described in paragraph (1); and

(E) the provision of technical assistance to providers of such services.

(c) LIMITATION ON DURATION OF GRANT.—The Secretary may make a grant under subsection (a) or (b) for not more than five consecutive one-year periods.

(d) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant under subsection (a) or (b) to an applicant unless the applicant agrees that not more than 10 percent of such a grant will be expended for administrative expenses.

(e) AUTHORIZATIONS OF APPROPRIATIONS.—

(1) For the purposes of carrying out this section, there are authorized to be appropriated \$50,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(2) Of the amounts appropriated pursuant to paragraph (1), the Secretary shall make available 15 percent for demonstration projects to carry out the purpose of this section in rural areas.

SEC. 520B. [290bb-33] DEMONSTRATION PROJECTS FOR INDIVIDUALS WITH POSITIVE TEST RESULTS.

(a) IN GENERAL.—The Secretary, acting through the Director of the Center for Mental Health Services, may make grants to public and nonprofit private entities for demonstration projects for the development, establishment, or expansion of programs to provide counseling and mental health treatment—

(1) for individuals who experience serious psychological reactions as a result of being informed that the results of testing for the etiologic agent for acquired immune deficiency syndrome indicate that the individuals are infected with such etiologic agent; and

(2) for the families of such individuals, and for others, who experience serious psychological reactions as a result of being informed of the results of such testing of such individuals.

(b) PREFERENCES IN MAKING GRANTS.—In making grants under subsection (a), the Secretary shall give preference to applicants that are based at, or have relationships with, entities providing comprehensive health services to individuals who are infected with the etiologic agent for acquired immune deficiency syndrome.

(c) REQUIREMENT OF PROVISION OF INFORMATION ON PREVENTION.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that counseling provided pursuant to such subsection will include counseling relating to measures for the prevention of exposure to, and the transmission of, the etiologic agent for acquired immune deficiency syndrome.

(d) AUTHORITY FOR TRAINING.—A grantee under subsection (a) may expend the grant to train individuals to provide the services described in such subsection.

(e) REQUIREMENT OF IDENTIFICATION OF NEEDS AND OBJECTIVES.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant submits to the Secretary—

(1) information demonstrating that the applicant has, with respect to mental health treatment related to the etiologic agent for acquired immune deficiency syndrome, identified the need for such treatment in the area in which the program will be developed, established, or expanded; and

(2) a description of—

(A) the objectives established by the applicant for the conduct of the program; and

(B) the method the applicant will use to evaluate the activities conducted under the program and to determine the extent to which such objectives have been met.

(f) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless—

(1) an application for the grant is submitted to the Secretary;

(2) with respect to carrying out the purpose for which the grant is to be made, the application provides assurances of compliance satisfactory to the Secretary;

(3) the application contains the information required to be submitted under subsection (e); and

(4) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(g) REQUIREMENT OF MINIMUM NUMBER OF GRANTS FOR FISCAL YEAR 1989.—Subject to the extent of amounts made available in appropriations Acts, the Secretary shall, for fiscal year 1989, make not less than 6 grants under subsection (a).

(h) TECHNICAL ASSISTANCE AND ADMINISTRATIVE SUPPORT.—The Secretary, acting through the Director of the National Institute of Mental Health, may provide technical assistance and administrative support to grantees under subsection (a).

(i) DEFINITION.—For purposes of this section, the term “mental health treatment” means individual, family or group services designed to alleviate distress, improve functional ability, or assist in changing dysfunctional behavior patterns.

(j) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1994.

PART C—PROJECTS FOR ASSISTANCE IN TRANSITION FROM HOMELESSNESS

SEC. 521. [290cc-21] FORMULA GRANTS TO STATES.

For the purpose of carrying out section 522, the Secretary, acting through the Director of the Center for Mental Health Services, shall for each of the fiscal years 1991 through 1994 make an allotment for each State in an amount determined in accordance with section 524. The Secretary shall make payments, as grants, each such fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 529.

SEC. 522. [290cc-22] PURPOSE OF GRANTS.

(a) IN GENERAL.—The Secretary may not make payments under section 521 unless the State involved agrees that the payments will be expended solely for making grants to political subdivisions of the State, and to nonprofit private entities (including community-based veterans organizations and other community organizations), for the purpose of providing the services specified in subsection (b) to individuals who—

(1)(A) are suffering from serious mental illness; or

(B) are suffering from serious mental illness and from substance abuse; and

(2) are homeless or at imminent risk of becoming homeless.

(b) SPECIFICATION OF SERVICES.—The services referred to in subsection (a) are—

(1) outreach services;

(2) screening and diagnostic treatment services;

(3) habilitation and rehabilitation services;

(4) community mental health services;

(5) alcohol or drug treatment services;

(6) staff training, including the training of individuals who work in shelters, mental health clinics, substance abuse programs, and other sites where homeless individuals require services;

(7) case management services, including—

(A) preparing a plan for the provision of community mental health services to the eligible homeless individual involved, and reviewing such plan not less than once every 3 months;

(B) providing assistance in obtaining and coordinating social and maintenance services for the eligible homeless individuals, including services relating to daily living activities, personal financial planning, transportation services, and habilitation and rehabilitation services, prevocational and vocational services, and housing services;

(C) providing assistance to the eligible homeless individual in obtaining income support services, including housing assistance, food stamps, and supplemental security income benefits;

(D) referring the eligible homeless individual for such other services as may be appropriate; and

(E) providing representative payee services in accordance with section 1631(a)(2) of the Social Security Act if the eligible homeless individual is receiving aid under title XVI of such act and if the applicant is designated by the Secretary to provide such services;

(8) supportive and supervisory services in residential settings;

(9) referrals for primary health services, job training, educational services, and relevant housing services;

(10) subject to subsection (h)(1)—

(A) minor renovation, expansion, and repair of housing;

(B) planning of housing;

(C) technical assistance in applying for housing assistance;

(D) improving the coordination of housing services;

(E) security deposits;

(F) the costs associated with matching eligible homeless individuals with appropriate housing situations; and

(G) 1-time rental payments to prevent eviction; and

(11) other appropriate services, as determined by the Secretary.

(c) COORDINATION.—The Secretary may not make payments under section 521 unless the State involved agrees to make grants pursuant to subsection (a) only to entities that have the capacity to provide, directly or through arrangements, the services specified in section 522(b), including coordinating the provision of services in order to meet the needs of eligible homeless individuals who are both mentally ill and suffering from substance abuse.

(d) SPECIAL CONSIDERATION REGARDING VETERANS.—The Secretary may not make payments under section 521 unless the State involved agrees that, in making grants to entities pursuant to subsection (a), the State will give special consideration to entities with a demonstrated effectiveness in serving homeless veterans.

(e) SPECIAL RULES.—The Secretary may not make payments under section 521 unless the State involved agrees that grants pursuant to subsection (a) will not be made to any entity that—

(1) has a policy of excluding individuals from mental health services due to the existence or suspicion of substance abuse; or

(2) has a policy of excluding individuals from substance abuse services due to the existence or suspicion of mental illness.

(f) **ADMINISTRATIVE EXPENSES.**—The Secretary may not make payments under section 521 unless the State involved agrees that not more than 4 percent of the payments will be expended for administrative expenses regarding the payments.

(g) **MAINTENANCE OF EFFORT.**—The Secretary may not make payments under section 521 unless the State involved agrees that the State will maintain State expenditures for services specified in subsection (b) at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying to receive such payments.

(h) **RESTRICTIONS ON USE OF FUNDS.**—The Secretary may not make payments under section 521 unless the State involved agrees that—

(1) not more than 20 percent of the payments will be expended for housing services under subsection (b)(10); and

(2) the payments will not be expended—

(A) to support emergency shelters or construction of housing facilities;

(B) for inpatient psychiatric treatment costs or inpatient substance abuse treatment costs; or

(C) to make cash payments to intended recipients of mental health or substance abuse services.

SEC. 523. [290cc-23] REQUIREMENT OF MATCHING FUNDS.

(a) **IN GENERAL.**—The Secretary may not make payments under section 521 unless, with respect to the costs of providing services pursuant to section 522, the State involved agrees to make available, directly or through donations from public or private entities, non-Federal contributions toward such costs in an amount that is not less than \$1 for each \$3 of Federal funds provided in such payments.

(b) **DETERMINATION OF AMOUNT.**—Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, shall not be included in determining the amount of such non-Federal contributions.

(c) **LIMITATION REGARDING GRANTS BY STATES.**—The Secretary may not make payments under section 521 unless the State involved agrees that the State will not require the entities to which grants are provided pursuant to section 522(a) to provide non-Federal contributions in excess of the non-Federal contributions described in subsection (a).

SEC. 524. [290cc-24] DETERMINATION OF AMOUNT OF ALLOTMENT.

(a) **MINIMUM ALLOTMENT.**—The allotment for a State under section 521 for a fiscal year shall be the greater of—

(1) \$300,000 for each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, and \$50,000 for each of Guam, the Virgin Islands, American Samoa, and the Commonwealth of the Northern Mariana Islands; and

(2) an amount determined in accordance with subsection

(b).

(b) DETERMINATION UNDER FORMULA.—The amount referred to in subsection (a)(2) is the product of—

(1) an amount equal to the amount appropriated under section 535(a) for the fiscal year; and

(2) a percentage equal to the quotient of—

(A) an amount equal to the population living in urbanized areas of the State involved, as indicated by the most recent data collected by the Bureau of the Census; and

(B) an amount equal to the population living in urbanized areas of the United States, as indicated by the sum of the respective amounts determined for the States under subparagraph (A).

SEC. 525. [290cc-25] CONVERSION TO CATEGORICAL PROGRAM IN EVENT OF FAILURE OF STATE REGARDING EXPENDITURE OF GRANTS.

(a) IN GENERAL.—Subject to subsection (c), the Secretary shall, from the amounts specified in subsection (b), make grants to public and nonprofit private entities for the purpose of providing to eligible homeless individuals the services specified in section 522(b).

(b) SPECIFICATION OF FUNDS.—The amounts referred to in subsection (a) are any amounts made available in appropriations Acts for allotments under section 521 that are not paid to a State as a result of—

(A) the failure of the State to submit an application under section 529;

(B) the failure of the State, in the determination of the Secretary, to prepare the application in accordance with such section or to submit the application within a reasonable period of time; or

(C) the State informing the Secretary that the State does not intend to expend the full amount of the allotment made to the State.

(c) REQUIREMENT OF PROVISION OF SERVICES IN STATE INVOLVED.—With respect to grants under subsection (a), amounts made available under subsection (b) as a result of the State involved shall be available only for grants to provide services in such State.

SEC. 526. [290cc-26] PROVISION OF CERTAIN INFORMATION FROM STATE.

The Secretary may not make payments under section 521 to a State unless, as part of the application required in section 529, the State submits to the Secretary a statement—

(1) identifying existing programs providing services and housing to eligible homeless individuals and identify gaps in the delivery systems of such programs;

(2) containing a plan for providing services and housing to eligible homeless individuals, which plan—

(A) describes the coordinated and comprehensive means of providing services and housing to homeless individuals; and

(B) includes documentation that suitable housing for eligible homeless individuals will accompany the provision of services to such individuals;

(3) describes the source of the non-Federal contributions described in section 523;

(4) contains assurances that the non-Federal contributions described in section 523 will be available at the beginning of the grant period;

(5) describe any voucher system that may be used to carry out this part; and

(6) contain such other information or assurances as the Secretary may reasonably require.

SEC. 527. [290cc-27] DESCRIPTION OF INTENDED EXPENDITURES OF GRANT.

(a) **IN GENERAL.**—The Secretary may not make payments under section 521 unless—

(1) as part of the application required in section 529, the State involved submits to the Secretary a description of the intended use for the fiscal year of the amounts for which the State is applying pursuant to such section;

(2) such description identifies the geographic areas within the State in which the greatest numbers of homeless individuals with a need for mental health, substance abuse, and housing services are located;

(3) such description provides information relating to the programs and activities to be supported and services to be provided, including information relating to coordinating such programs and activities with any similar programs and activities of public and private entities; and

(4) the State agrees that such description will be revised throughout the year as may be necessary to reflect substantial changes in the programs and activities assisted by the State pursuant to section 522.

(b) **OPPORTUNITY FOR PUBLIC COMMENT.**—The Secretary may not make payments under section 521 unless the State involved agrees that, in developing and carrying out the description required in subsection (a), the State will provide public notice with respect to the description (including any revisions) and such opportunities as may be necessary to provide interested persons, such as family members, consumers, and mental health, substance abuse, and housing agencies, an opportunity to present comments and recommendations with respect to the description.

(c) **RELATIONSHIP TO STATE COMPREHENSIVE MENTAL HEALTH SERVICES PLAN.**—

(1) **IN GENERAL.**—The Secretary may not make payments under section 521 unless the services to be provided pursuant to the description required in subsection (a) are consistent with the State comprehensive mental health services plan required in subpart 2 of part B of title XIX.

(2) **SPECIAL RULE.**—The Secretary may not make payments under section 521 unless the services to be provided pursuant to the description required in subsection (a) have been considered in the preparation of, have been included in, and are con-

sistent with, the State comprehensive mental health services plan referred to in paragraph (1).

SEC. 528. [290cc-28] REQUIREMENT OF REPORTS BY STATES.

(a) **IN GENERAL.**—The Secretary may not make payments under section 521 unless the State involved agrees that, by not later than January 31 of each fiscal year, the State will prepare and submit to the Secretary a report in such form and containing such information as the Secretary determines (after consultation with the Comptroller General of the United States, and the Administrator of the Substance Abuse and Mental Health Services Administration) to be necessary for—

(1) securing a record and a description of the purposes for which amounts received under section 521 were expended during the preceding fiscal year and of the recipients of such amounts; and

(2) determining whether such amounts were expended in accordance with the provisions of this part.

(b) **AVAILABILITY TO PUBLIC OF REPORTS.**—The Secretary may not make payments under section 521 unless the State involved agrees to make copies of the reports described in subsection (a) available for public inspection.

(c) **EVALUATIONS BY COMPTROLLER GENERAL.**—The Comptroller General of the United States in cooperation with the Administrator of the Substance Abuse and Mental Health Services Administration, shall evaluate at least once every 3 years the expenditures of grants under this part by eligible entities in order to ensure that expenditures are consistent with the provisions of this part, and shall include in such evaluation recommendations regarding changes needed in program design or operations.

SEC. 529. [290cc-29] REQUIREMENT OF APPLICATION.

The Secretary may not make payments under section 521 unless the State involved—

(1) submits to the Secretary an application for the payments containing agreements and information in accordance with this part;

(2) the agreements are made through certification from the chief executive officer of the State; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

SEC. 530. [290cc-30] TECHNICAL ASSISTANCE.

The Secretary, through¹ the National Institute of Mental Health, the National Institute of Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse, shall provide technical

¹ Section 162(2) of Public Law 102-321 (106 Stat. 375) provides that section 530 is amended by striking out "through the National" and all that follows through "Abuse" and inserting in lieu thereof "through the agencies of the Administration". The amendment cannot be executed because it does not specify to which instance of the term "Abuse" the amendment applies. Additionally, section 163(a)(3) of such law described an amendment that could not be executed, as the amendment included instructions to strike "on Alcohol Abuse" while "of Alcohol Abuse" is the term in section 530. This latter amendment purported to insert "Administrator of the Substance Abuse and Mental Health Services Administration". Subsequently, such section 163(a)(3) was struck by section 2(b)(2) of Public Law 102-352 (106 Stat. 939).

assistance to eligible entities in developing planning and operating programs in accordance with the provisions of this part.

SEC. 531. [290cc-31] FAILURE TO COMPLY WITH AGREEMENTS.

(a) REPAYMENT OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), require a State to repay any payments received by the State under section 521 that the Secretary determines were not expended by the State in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 529.

(2) If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against the amount of any payment due to be paid to the State under section 521.

(b) WITHHOLDING OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), withhold payments due under section 521 if the Secretary determines that the State involved is not expending amounts received under such section in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 529.

(2) The Secretary shall cease withholding payments from a State under paragraph (1) if the Secretary determines that there are reasonable assurances that the State will expend amounts received under section 521 in accordance with the agreements referred to in such paragraph.

(3) The Secretary may not withhold funds under paragraph (1) from a State for a minor failure to comply with the agreements referred to in such paragraph.

(c) OPPORTUNITY FOR HEARING.—Before requiring repayment of payments under subsection (a)(1), or withholding payments under subsection (b)(1), the Secretary shall provide to the State an opportunity for a hearing.

(d) RULE OF CONSTRUCTION.—Notwithstanding any other provision of this part, a State receiving payments under section 521 may not, with respect to any agreements required to be contained in the application submitted under section 529, be considered to be in violation of any such agreements by reason of the fact that the State, in the regular course of providing services under section 522(b) to eligible homeless individuals, incidentally provides services to homeless individuals who are not eligible homeless individuals.

SEC. 532. [290cc-32] PROHIBITION AGAINST CERTAIN FALSE STATEMENTS.

(a) IN GENERAL.—

(1) A person may not knowingly make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which amounts may be paid by a State from payments received by the State under section 521.

(2) A person with knowledge of the occurrence of any event affecting the right of the person to receive any amounts from payments made to the State under section 521 may not conceal

or fail to disclose any such event with the intent of securing such an amount that the person is not authorized to receive or securing such an amount in an amount greater than the amount the person is authorized to receive.

(b) CRIMINAL PENALTY FOR VIOLATION OF PROHIBITION.—Any person who violates a prohibition established in subsection (a) may for each violation be fined in accordance with title 18, United States Code, or imprisoned for not more than 5 years, or both.

SEC. 533. [290cc-33] NONDISCRIMINATION.

(a) IN GENERAL.—

(1) RULE OF CONSTRUCTION REGARDING CERTAIN CIVIL RIGHTS LAWS.—For the purpose of applying the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975, on the basis of handicap under section 504 of the Rehabilitation Act of 1973, on the basis of sex under title IX of the Education Amendments of 1972, or on the basis of race, color, or national origin under title VI of the Civil Rights Act of 1964, programs and activities funded in whole or in part with funds made available under section 521 shall be considered to be programs and activities receiving Federal financial assistance.

(2) PROHIBITION.—No person shall on the ground of sex or religion be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity funded in whole or in part with funds made available under section 521.

(b) ENFORCEMENT.—

(1) REFERRALS TO ATTORNEY GENERAL AFTER NOTICE.—Whenever the Secretary finds that a State, or an entity that has received a payment pursuant to section 521, has failed to comply with a provision of law referred to in subsection (a)(1), with subsection (a)(2), or with an applicable regulation (including one prescribed to carry out subsection (a)(2)), the Secretary shall notify the chief executive officer of the State and shall request the chief executive officer to secure compliance. If within a reasonable period of time, not to exceed 60 days, the chief executive officer fails or refuses to secure compliance, the Secretary may—

(A) refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted;

(B) exercise the powers and functions provided by the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, title IX of the Education Amendments of 1972, or title VI of the Civil Rights Act of 1964, as may be applicable; or

(C) take such other actions as may be authorized by law.

(2) AUTHORITY OF ATTORNEY GENERAL.—When a matter is referred to the Attorney General pursuant to paragraph (1)(A), or whenever the Attorney General has reason to believe that a State or an entity is engaged in a pattern or practice in violation of a provision of law referred to in subsection (a)(1) or in

violation of subsection (a)(2), the Attorney General may bring a civil action in any appropriate district court of the United States for such relief as may be appropriate, including injunctive relief.

SEC. 534. [290cc-34] DEFINITIONS.

For purposes of this part:

(1) **ELIGIBLE HOMELESS INDIVIDUAL.**—The term “eligible homeless individual” means an individual described in section 522(a).

(2) **HOMELESS INDIVIDUAL.**—The term “homeless individual” has the meaning given such term in section 340(r).

(3) **STATE.**—The term “State” means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(4) **SUBSTANCE ABUSE.**—The term “substance abuse” means the abuse of alcohol or other drugs.

SEC. 535. [290cc-35] FUNDING.

(a) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this part, there is authorized to be appropriated \$75,000,000 for each of the fiscal years 1991 through 1994.

(b) **EFFECT OF INSUFFICIENT APPROPRIATIONS FOR MINIMUM ALLOTMENTS.**—

(1) **IN GENERAL.**—If the amounts made available under subsection (a) for a fiscal year are insufficient for providing each State with an allotment under section 521 of not less than the applicable amount under section 524(a)(1), the Secretary shall, from such amounts as are made available under such subsection, make grants to the States for providing to eligible homeless individuals the services specified in section 522(b).

(2) **RULE OF CONSTRUCTION.**—Paragraph (1) may not be construed to require the Secretary to make a grant under such paragraph to each State.

PART D—MISCELLANEOUS PROVISIONS RELATING TO SUBSTANCE ABUSE AND MENTAL HEALTH

SEC. 541. [290dd] SUBSTANCE ABUSE AMONG GOVERNMENT AND OTHER EMPLOYEES.

(a) **PROGRAMS AND SERVICES.**—

(1) **DEVELOPMENT.**—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall be responsible for fostering substance abuse prevention and treatment programs and services in State and local governments and in private industry.

(2) **MODEL PROGRAMS.**—

(A) **IN GENERAL.**—Consistent with the responsibilities described in paragraph (1), the Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall develop a variety of model programs suitable for replication on a cost-effective basis in different types of business concerns and State and local governmental entities.

(B) DISSEMINATION OF INFORMATION.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall disseminate information and materials relative to such model programs to the State agencies responsible for the administration of substance abuse prevention, treatment, and rehabilitation activities and shall, to the extent feasible provide technical assistance to such agencies as requested.

(b) DEPRIVATION OF EMPLOYMENT.—

(1) PROHIBITION.—No person may be denied or deprived of Federal civilian employment or a Federal professional or other license or right solely on the grounds of prior substance abuse.

(2) APPLICATION.—This subsection shall not apply to employment in—

(A) the Central Intelligence Agency;

(B) the Federal Bureau of Investigation;

(C) the National Security Agency;

(D) any other department or agency of the Federal Government designated for purposes of national security by the President; or

(E) in any position in any department or agency of the Federal Government, not referred to in subparagraphs (A) through (D), which position is determined pursuant to regulations prescribed by the head of such agency or department to be a sensitive position.

(3) REHABILITATION ACT.—The inapplicability of the prohibition described in paragraph (1) to the employment described in paragraph (2) shall not be construed to reflect on the applicability of the Rehabilitation Act of 1973 or other anti-discrimination laws to such employment.

(c) CONSTRUCTION.—This section shall not be construed to prohibit the dismissal from employment of a Federal civilian employee who cannot properly function in his employment.

SEC. 542. [290dd-1] ADMISSION OF SUBSTANCE ABUSERS TO PRIVATE AND PUBLIC HOSPITALS AND OUTPATIENT FACILITIES.

(a) NONDISCRIMINATION.—Substance abusers who are suffering from medical conditions shall not be discriminated against in admission or treatment, solely because of their substance abuse, by any private or public general hospital, or outpatient facility (as defined in section 1624(4)) which receives support in any form from any program supported in whole or in part by funds appropriated to any Federal department or agency.

(b) REGULATIONS.—

(1) IN GENERAL.—The Secretary shall issue regulations for the enforcement of the policy of subsection (a) with respect to the admission and treatment of substance abusers in hospitals and outpatient facilities which receive support of any kind from any program administered by the Secretary. Such regulations shall include procedures for determining (after opportunity for a hearing if requested) if a violation of subsection (a) has occurred, notification of failure to comply with such subsection, and opportunity for a violator to comply with such subsection. If the Secretary determines that a hospital or outpatient facility subject to such regulations has violated sub-

section (a) and such violation continues after an opportunity has been afforded for compliance, the Secretary may suspend or revoke, after opportunity for a hearing, all or part of any support of any kind received by such hospital from any program administered by the Secretary. The Secretary may consult with the officials responsible for the administration of any other Federal program from which such hospital or outpatient facility receives support of any kind, with respect to the suspension or revocation of such other Federal support for such hospital or outpatient facility.

(2) DEPARTMENT OF VETERANS AFFAIRS.—The Secretary of Veterans Affairs, acting through the Under Secretary for Health, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations prescribed by the Secretary under paragraph (1) to the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from substance abuse. In prescribing and implementing regulations pursuant to this paragraph, the Secretary shall, from time to time, consult with the Secretary of Health and Human Services in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

SEC. 543. [290dd-2] CONFIDENTIALITY OF RECORDS.

(a) REQUIREMENT.—Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b).

(b) PERMITTED DISCLOSURE.—

(1) CONSENT.—The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).

(2) METHOD FOR DISCLOSURE.—Whether or not the patient, with respect to whom any given record referred to in subsection (a) is maintained, gives written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor, including the need to avert a substantial risk of death or serious bodily harm. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) USE OF RECORDS IN CRIMINAL PROCEEDINGS.—Except as authorized by a court order granted under subsection (b)(2)(C), no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) APPLICATION.—The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when such individual ceases to be a patient.

(e) NONAPPLICABILITY.—The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Department of Veterans Affairs furnishing health care to veterans; or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) PENALTIES.—Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with title 18, United States Code.

(g) REGULATIONS.—Except as provided in subsection (h), the Secretary shall prescribe regulations to carry out the purposes of this section. Such regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C), as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(h) APPLICATION TO DEPARTMENT OF VETERANS AFFAIRS.—The Secretary of Veterans Affairs, acting through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations prescribed by the Secretary of Health and Human Services under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from substance abuse. In prescribing and implementing regulations pursuant to this subsection, the Secretary of Veterans Affairs shall, from time to time, consult with the Secretary of Health and Human Services

in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

PART E—CHILDREN WITH SERIOUS EMOTIONAL DISTURBANCES

SEC. 561. [290ff] COMPREHENSIVE COMMUNITY MENTAL HEALTH SERVICES FOR CHILDREN WITH SERIOUS EMOTIONAL DISTURBANCES.

(a) GRANTS TO CERTAIN PUBLIC ENTITIES.—

(1) **IN GENERAL.**—The Secretary, acting through the Director of the Center for Mental Health Services, shall make grants to public entities for the purpose of providing comprehensive community mental health services to children with a serious emotional disturbance.

(2) **DEFINITION OF PUBLIC ENTITY.**—For purposes of this part, the term “public entity” means any State, any political subdivision of a State, and any Indian tribe or tribal organization (as defined in section 4(b) and section 4(c) of the Indian Self-Determination and Education Assistance Act).

(b) CONSIDERATIONS IN MAKING GRANTS.—

(1) **REQUIREMENT OF STATUS AS GRANTEE UNDER PART B OF TITLE XIX.**—The Secretary may make a grant under subsection (a) to a public entity only if—

(A) in the case of a public entity that is a State, the State is such a grantee under section 1911;

(B) in the case of a public entity that is a political subdivision of a State, the State in which the political subdivision is located is such a grantee; and

(C) in the case of a public entity that is an Indian tribe or tribal organization, the State in which the tribe or tribal organization is located is such a grantee.

(2) **REQUIREMENT OF STATUS AS MEDICAID PROVIDER.—**

(A) Subject to subparagraph (B), the Secretary may make a grant under subsection (a) only if, in the case of any service under such subsection that is covered in the State plan approved under title XIX of the Social Security Act for the State involved—

(i) the public entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the public entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under subsection (a), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any in-

surance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(3) CERTAIN CONSIDERATIONS.—In making grants under subsection (a), the Secretary shall—

(A) equitably allocate such assistance among the principal geographic regions of the United States;

(B) consider the extent to which the public entity involved has a need for the grant; and

(C) in the case of any public entity that is a political subdivision of a State or that is an Indian tribe or tribal organization—

(i) shall consider any comments regarding the application of the entity for such a grant that are received by the Secretary from the State in which the entity is located; and

(ii) shall give special consideration to the entity if the State agrees to provide a portion of the non-Federal contributions required in subsection (c) regarding such a grant.

(c) MATCHING FUNDS.—

(1) IN GENERAL.—A funding agreement for a grant under subsection (a) is that the public entity involved will, with respect to the costs to be incurred by the entity in carrying out the purpose described in such subsection, make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that—

(A) for the first fiscal year for which the entity receives payments from a grant under such subsection, is not less than \$1 for each \$3 of Federal funds provided in the grant;

(B) for any second or third such fiscal year, is not less than \$1 for each \$3 of Federal funds provided in the grant;

(C) for any fourth such fiscal year, is not less than \$1 for each \$1 of Federal funds provided in the grant; and

(D) for any fifth such fiscal year, is not less than \$2 for each \$1 of Federal funds provided in the grant.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) In making a determination of the amount of non-Federal contributions for purposes of subparagraph (A), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contribu-

tions made by the public entity involved toward the purpose described in subsection (a) for the 2-year period preceding the first fiscal year for which the entity receives a grant under such section.

SEC. 562. [290ff-1] REQUIREMENTS WITH RESPECT TO CARRYING OUT PURPOSE OF GRANTS.

(a) SYSTEMS OF COMPREHENSIVE CARE.—

(1) **IN GENERAL.**—A funding agreement for a grant under section 561(a) is that, with respect to children with a serious emotional disturbance, the public entity involved will carry out the purpose described in such section only through establishing and operating 1 or more systems of care for making each of the mental health services specified in subsection (c) available to each child provided access to the system. In providing for such a system, the public entity may make grants to, and enter into contracts with, public and nonprofit private entities.

(2) **STRUCTURE OF SYSTEM.**—A funding agreement for a grant under section 561(a) is that a system of care under paragraph (1) will—

(A) be established in a community selected by the public entity involved;

(B) consist of such public agencies and nonprofit private entities in the community as are necessary to ensure that each of the services specified in subsection (c) is available to each child provided access to the system;

(C) be established pursuant to agreements that the public entity enters into with the agencies and entities described in subparagraph (B);

(D) coordinate the provision of the services of the system; and

(E) establish an office whose functions are to serve as the location through which children are provided access to the system, to coordinate the provision of services of the system, and to provide information to the public regarding the system.

(3) **COLLABORATION OF LOCAL PUBLIC ENTITIES.**—A funding agreement for a grant under section 561(a) is that, for purposes of the establishment and operation of a system of care under paragraph (1), the public entity involved will seek collaboration among all public agencies that provide human services in the community in which the system is established, including but not limited to those providing mental health services, educational services, child welfare services, or juvenile justice services.

(b) **LIMITATION ON AGE OF CHILDREN PROVIDED ACCESS TO SYSTEM.**—A funding agreement for a grant under section 561(a) is that a system of care under subsection (a) will not provide an individual with access to the system if the individual is more than 21 years of age.

(c) **REQUIRED MENTAL HEALTH SERVICES OF SYSTEM.**—A funding agreement for a grant under section 561(a) is that mental health services provided by a system of care under subsection (a) will include, with respect to a serious emotional disturbance in a child—

(1) diagnostic and evaluation services;

(2) outpatient services provided in a clinic, office, school or other appropriate location, including individual, group and family counseling services, professional consultation, and review and management of medications;

(3) emergency services, available 24-hours a day, 7 days a week;

(4) intensive home-based services for children and their families when the child is at imminent risk of out-of-home placement;

(5) intensive day-treatment services;

(6) respite care;

(7) therapeutic foster care services, and services in therapeutic foster family homes or individual therapeutic residential homes, and groups homes caring for not more than 10 children; and

(8) assisting the child in making the transition from the services received as a child to the services to be received as an adult.

(d) REQUIRED ARRANGEMENTS REGARDING OTHER APPROPRIATE SERVICES.—

(1) IN GENERAL.—A funding agreement for a grant under section 561(a) is that—

(A) a system of care under subsection (a) will enter into a memorandum of understanding with each of the providers specified in paragraph (2) in order to facilitate the availability of the services of the provider involved to each child provided access to the system; and

(B) the grant under such section 561(a), and the non-Federal contributions made with respect to the grant, will not be expended to pay the costs of providing such non-mental health services to any individual.

(2) SPECIFICATION OF NON-MENTAL HEALTH SERVICES.—The providers referred to in paragraph (1) are providers of medical services other than mental health services, providers of educational services, providers of vocational counseling and vocational rehabilitation services, and providers of protection and advocacy services with respect to mental health.

(3) FACILITATION OF SERVICES OF CERTAIN PROGRAMS.—A funding agreement for a grant under section 561(a) is that a system of care under subsection (a) will, for purposes of paragraph (1), enter into a memorandum of understanding regarding facilitation of—

(A) services available pursuant to title XIX of the Social Security Act, including services regarding early periodic screening, diagnosis, and treatment;

(B) services available under parts B and H of the Individuals with Disabilities Education Act; and

(C) services available under other appropriate programs, as identified by the Secretary.

(e) GENERAL PROVISIONS REGARDING SERVICES OF SYSTEM.—

(1) CASE MANAGEMENT SERVICES.—A funding agreement for a grant under section 561(a) is that a system of care under

subsection (a) will provide for the case management of each child provided access to the system in order to ensure that—

(A) the services provided through the system to the child are coordinated and that the need of each such child for the services is periodically reassessed;

(B) information is provided to the family of the child on the extent of progress being made toward the objectives established for the child under the plan of services implemented for the child pursuant to section 563; and

(C) the system provides assistance with respect to—

(i) establishing the eligibility of the child, and the family of the child, for financial assistance and services under Federal, State, or local programs providing for health services, mental health services, educational services, social services, or other services; and

(ii) seeking to ensure that the child receives appropriate services available under such programs.

(2) OTHER PROVISIONS.—A funding agreement for a grant under section 561(a) is that a system of care under subsection (a), in providing the services of the system, will—

(A) provide the services of the system in the cultural context that is most appropriate for the child and family involved;

(B) ensure that individuals providing such services to the child can effectively communicate with the child and family in the most direct manner;

(C) provide the services without discriminating against the child or the family of the child on the basis of race, religion, national origin, sex, disability, or age;

(D) seek to ensure that each child provided access to the system of care remains in the least restrictive, most normative environment that is clinically appropriate; and

(E) provide outreach services to inform individuals, as appropriate, of the services available from the system, including identifying children with a serious emotional disturbance who are in the early stages of such disturbance.

(3) RULE OF CONSTRUCTION.—An agreement made under paragraph (2) may not be construed—

(A) with respect to subparagraph (C) of such paragraph—

(i) to prohibit a system of care under subsection (a) from requiring that, in housing provided by the grantee for purposes of residential treatment services authorized under subsection (c), males and females be segregated to the extent appropriate in the treatment of the children involved; or

(ii) to prohibit the system of care from complying with the agreement made under subsection (b); or

(B) with respect to subparagraph (D) of such paragraph, to authorize the system of care to expend the grant under section 561(a) (or the non-Federal contributions made with respect to the grant) to provide legal services or any service with respect to which expenditures regarding the grant are prohibited under subsection (d)(1)(B).

(f) **RESTRICTIONS ON USE OF GRANT.**—A funding agreement for a grant under section 561(a) is that the grant, and the non-Federal contributions made with respect to the grant, will not be expended—

(1) to purchase or improve real property (including the construction or renovation of facilities);

(2) to provide for room and board in residential programs serving 10 or fewer children;

(3) to provide for room and board or other services or expenditures associated with care of children in residential treatment centers serving more than 10 children or in inpatient hospital settings, except intensive home-based services and other services provided on an ambulatory or outpatient basis; or

(4) to provide for the training of any individual, except training authorized in section 564(a)(2) and training provided through any appropriate course in continuing education whose duration does not exceed 2 days.

SEC. 563. [290ff-2] INDIVIDUALIZED PLAN FOR SERVICES.

(a) **IN GENERAL.**—A funding agreement for a grant under section 561(a) is that a system of care under section 562(a) will develop and carry out an individualized plan of services for each child provided access to the system, and that the plan will be developed and carried out with the participation of the family of the child and, unless clinically inappropriate, with the participation of the child.

(b) **MULTIDISCIPLINARY TEAM.**—A funding agreement for a grant under section 561(a) is that the plan required in subsection (a) will be developed, and reviewed and as appropriate revised not less than once each year, by a multidisciplinary team of appropriately qualified individuals who provide services through the system, including as appropriate mental health services, other health services, educational services, social services, and vocational counseling and rehabilitation;

(c) **COORDINATION WITH SERVICES UNDER INDIVIDUALS WITH DISABILITIES EDUCATION ACT.**—A funding agreement for a grant under section 561(a) is that, with respect to a plan under subsection (a) for a child, the multidisciplinary team required in subsection (b) will—

(1) in developing, carrying out, reviewing, and revising the plan consider any individualized education program in effect for the child pursuant to part B of the Individuals with Disabilities Education Act;

(2) ensure that the plan is consistent with such individualized education program and provides for coordinating services under the plan with services under such program; and

(3) ensure that the memorandum of understanding entered into under section 562(d)(3)(B) regarding such Act includes provisions regarding compliance with this subsection.

(d) **CONTENTS OF PLAN.**—A funding agreement for a grant under section 561(a) is that the plan required in subsection (a) for a child will—

(1) identify and state the needs of the child for the services available pursuant to section 562 through the system;

(2) provide for each of such services that is appropriate to the circumstances of the child, including, except in the case of children who are less than 14 years of age, the provision of appropriate vocational counseling and rehabilitation, and transition services (as defined in section 602(a)(19) of the Individuals with Disabilities Education Act);

(3) establish objectives to be achieved regarding the needs of the child and the methodology for achieving the objectives; and

(4) designate an individual to be responsible for providing the case management required in section 562(e)(1) or certify that case management services will be provided to the child as part of the individualized education program of the child under the Individuals with Disabilities Education Act.

SEC. 564. [290ff-3] ADDITIONAL PROVISIONS.

(a) **OPTIONAL SERVICES.**—In addition to services described in subsection (c) of section 562, a system of care under subsection (a) of such section may, in expending a grant under section 561(a), provide for—

(1) preliminary assessments to determine whether a child should be provided access to the system;

(2) training in—

(A) the administration of the system;

(B) the provision of intensive home-based services under paragraph (4) of section 562(c), intensive day treatment under paragraph (5) of such section, and foster care or group homes under paragraph (7) of such section; and

(C) the development of individualized plans for purposes of section 563;

(3) recreational activities for children provided access to the system; and

(4) such other services as may be appropriate in providing for the comprehensive needs with respect to mental health of children with a serious emotional disturbance.

(b) **COMPREHENSIVE PLAN.**—The Secretary may make a grant under section 561(a) only if, with respect to the jurisdiction of the public entity involved, the entity has submitted to the Secretary, and has had approved by the Secretary, a plan for the development of a jurisdiction-wide system of care for community-based services for children with a serious emotional disturbance that specifies the progress the public entity has made in developing the jurisdiction-wide system, the extent of cooperation across agencies serving children in the establishment of the system, the Federal and non-Federal resources currently committed to the establishment of the system, and the current gaps in community services and the manner in which the grant under section 561(a) will be expended to address such gaps and establish local systems of care.

(c) **LIMITATION ON IMPOSITION OF FEES FOR SERVICES.**—A funding agreement for a grant under section 561(a) is that, if a charge is imposed for the provision of services under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the family of the child involved; and

(3) will not be imposed on any child whose family has income and resources of equal to or less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(d) **RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.**—A funding agreement for a grant under section 561(a) is that the grant, and the non-Federal contributions made with respect to the grant, will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(e) **LIMITATION ON ADMINISTRATIVE EXPENSES.**—A funding agreement for a grant under section 561(a) is that not more than 2 percent of the grant will be expended for administrative expenses incurred with respect to the grant by the public entity involved.

(f) **REPORTS TO SECRETARY.**—A funding agreement for a grant under section 561(a) is that the public entity involved will annually submit to the Secretary a report on the activities of the entity under the grant that includes a description of the number of children provided access to systems of care operated pursuant to the grant, the demographic characteristics of the children, the types and costs of services provided pursuant to the grant, the availability and use of third-party reimbursements, estimates of the unmet need for such services in the jurisdiction of the entity, and the manner in which the grant has been expended toward the establishment of a jurisdiction-wide system of care for children with a serious emotional disturbance, and such other information as the Secretary may require with respect to the grant.

(g) **DESCRIPTION OF INTENDED USES OF GRANT.**—The Secretary may make a grant under section 561(a) only if—

(1) the public entity involved submits to the Secretary a description of the purposes for which the entity intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the jurisdiction of the entity with a need for services under this section; and

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public or nonprofit entities.

(h) **REQUIREMENT OF APPLICATION.**—The Secretary may make a grant under section 561(a) only if an application for the grant is

submitted to the Secretary, the application contains the description of intended uses required in subsection (g), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

SEC. 565. [290ff-4] GENERAL PROVISIONS.

(a) **DURATION OF SUPPORT.**—The period during which payments are made to a public entity from a grant under section 561(a) may not exceed 5 fiscal years.

(b) **TECHNICAL ASSISTANCE.**—

(1) **IN GENERAL.**—The Secretary shall, upon the request of a public entity receiving a grant under section 561(a)—

(A) provide technical assistance to the entity regarding the process of submitting to the Secretary applications for grants under section 561(a); and

(B) provide to the entity training and technical assistance with respect to the planning, development, and operation of systems of care pursuant to section 562.

(2) **AUTHORITY FOR GRANTS AND CONTRACTS.**—The Secretary may provide technical assistance under subsection (a) directly or through grants to, or contracts with, public and non-profit private entities.

(c) **EVALUATIONS AND REPORTS BY SECRETARY.**—

(1) **IN GENERAL.**—The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to section 561(a). The evaluations shall assess the effectiveness of the systems of care operated pursuant to such section, including longitudinal studies of outcomes of services provided by such systems, other studies regarding such outcomes, the effect of activities under this part on the utilization of hospital and other institutional settings, the barriers to and achievements resulting from inter-agency collaboration in providing community-based services to children with a serious emotional disturbance, and assessments by parents of the effectiveness of the systems of care.

(2) **REPORT TO CONGRESS.**—The Secretary shall, not later than 1 year after the date on which amounts are first appropriated under subsection (c), and annually thereafter, submit to the Congress a report summarizing evaluations carried out pursuant to paragraph (1) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this section as the Secretary determines to be appropriate.

(d) **DEFINITIONS.**—For purposes of this part:

(1) The term “child” means an individual not more than 21 years of age.

(2) The term “family”, with respect to a child provided access to a system of care under section 562(a), means—

(A) the legal guardian of the child; and

(B) as appropriate regarding mental health services for the child, the parents of the child (biological or adoptive, as the case may be) and any foster parents of the child.

(3) The term "funding agreement", with respect to a grant under section 561(a) to a public entity, means that the Secretary may make such a grant only if the public entity makes the agreement involved.

(4) The term "serious emotional disturbance" includes, with respect to a child, any child who has a serious emotional disorder, a serious behavioral disorder, or a serious mental disorder.

(e) **RULE OF CONSTRUCTION.**—Nothing in this part shall be construed as limiting the rights of a child with a serious emotional disturbance under the Individuals with Disabilities Education Act.

(f) **FUNDING.**—

(1) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this part, there are authorized to be appropriated \$100,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(2)¹ **LIMITATION REGARDING TECHNICAL ASSISTANCE.**—Not more than 10 percent of the amounts appropriated under paragraph (1) for a fiscal year may be expended for carrying out subsection (b).

PART F—MODEL COMPREHENSIVE PROGRAM FOR TREATMENT OF SUBSTANCE ABUSE

DEMONSTRATION PROGRAM IN NATIONAL CAPITAL AREA

SEC. 571. [290gg] (a) **IN GENERAL.**—The Secretary, in collaboration with the Director of the Treatment Center, shall make a demonstration grant for the establishment, within the national capital area, of a model program for providing comprehensive treatment services for substance abuse.

(b) **PURPOSES.**—The Secretary may not make a grant under subsection (a) unless, with respect to the comprehensive treatment services to be offered by the program under such subsection, the applicant for the grant agrees—

(1) to ensure, to the extent practicable, that the program has the capacity to provide the services to all individuals who seek and would benefit from the services;

(2) as appropriate, to provide education on obtaining employment and other matters with respect to assisting the individuals in preventing any relapse into substance abuse, including education on the appropriate involvement of parents and others in preventing such a relapse;

(3) to provide services in locations accessible to substance abusers and, to the extent practicable, to provide services through mobile facilities;

(4) to give priority to providing services to individuals who are intravenous drug abusers, to pregnant women, to homeless individuals, and to residents of publicly-assisted housing;

(5) with respect to women with dependent children, to provide child care to such women seeking treatment services for substance abuse;

(6) to conduct outreach activities to inform individuals of the availability of the services of the program;

¹ Indentation is so in law. See section 2017(2)(C)(ii) of Public Law 103-43 (107 Stat. 218).

(7) to provide case management services, including services to determine eligibility for assistance under Federal, State, and local programs providing health services, mental health services, or social services;

(8) to ensure the establishment of one or more offices to oversee the coordination of the activities of the program, to ensure that treatment is available to those seeking it, to ensure that the program is administered efficiently, and to ensure that the public is informed that the offices are the locations at which individuals may make inquiries concerning the program, including the location of available treatment services within the national capital area; and

(9) to develop and utilize standards for certifying the knowledge and training of individuals, and the quality of programs, to provide treatment services for substance abuse.

(c) CERTAIN REQUIREMENTS.—

(1) REGARDING ELIGIBILITY FOR GRANT.—

(A) The Secretary may not make the grant under subsection (a) unless the applicant involved is an organization of the general-purpose local governments within the national capital area, or another public or nonprofit private entity, and the applicant submits to the Secretary assurances satisfactory to the Secretary that, with respect to the communities in which services will be offered, the local governments of the communities will participate in the program.

(B) The Secretary may not make the grant under subsection (a) unless—

(i) an application for the grant is submitted to the Secretary;

(ii) with respect to carrying out the purpose for which the grant is to be made, the application provides assurances of compliance satisfactory to the Secretary; and

(iii) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(2) AUTHORITY FOR COOPERATIVE AGREEMENTS.—The grantee under subsection (a) may provide the services required by such subsection directly or through arrangements with public and nonprofit private entities.

(d) REQUIREMENT OF NON-FEDERAL CONTRIBUTIONS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such subsection, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount not less than \$1 for each \$2 of Federal funds provided under the grant.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or serv-

ices. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(e) EVALUATIONS.—

(1) BY SECRETARY.—The Secretary shall independently evaluate the effectiveness of the program carried out under subsection (a) and determine its suitability as a model for the United States, particularly regarding the provision of high quality, patient-oriented, coordinated and accessible drug treatment services across jurisdictional lines. The Secretary shall consider the extent to which the program has improved patient retention, accessibility of services, staff retention and quality, reduced patient relapse, and provided a full range of drug treatment and related health and human services. The Secretary shall evaluate the extent to which the program has effectively utilized innovative methods for overcoming the resistance of the residents of communities to the establishment of treatment facilities within the communities.

(2) BY GRANTEE.—The Secretary may require the grantee under subsection (a) to evaluate any aspect of the program carried out under such subsection, and such evaluation shall, to the extent appropriate, be coordinated with the independent evaluation required in paragraph (1).

(3) LIMITATION.—Funds made available under subsection (h) may not be utilized to conduct the independent evaluation required in paragraph (1).

(f) REPORTS.—

(1) INITIAL CRITERIA.—The Secretary shall make a determination of the appropriate criteria for carrying out the program required in subsection (a), including the anticipated need for, and range of, services under the program in the communities involved and the anticipated costs of the program. Not later than 90 days after the date of the enactment of the ADAMHA Reorganization Act, the Secretary shall submit to the Congress a report describing the findings made as a result of the determination.

(2) ANNUAL REPORTS.—Not later than 2 years after the date on which the grant is made under subsection (a), and annually thereafter, the Secretary shall submit to the Congress a report describing the extent to which the program carried out under such subsection has been effective in carrying out the purposes of the program.

(g) DEFINITION.—For purposes of this section, the term “national capital area” means the metropolitan Washington area, including the District of Columbia, the cities of Alexandria, Falls Church, and Fairfax in the State of Virginia, the counties of Arlington and Fairfax in such State (and the political subdivisions located in such counties), and the counties of Montgomery and Prince George’s in the State of Maryland (and the political subdivisions located in such counties).

(h) OBLIGATION OF FUNDS.—Of the amounts appropriated for each of the fiscal years 1993 and 1994 for the programs of the Department of Health and Human Services, the Secretary shall make

available \$10,000,000 for carrying out this section. Of the amounts appropriated for fiscal year 1995 for the programs of such Department, the Secretary shall make available \$5,000,000 for carrying out this section.

TITLE VI—ASSISTANCE FOR CONSTRUCTION AND MODERNIZATION OF HOSPITALS AND OTHER MEDICAL FACILITIES

DECLARATION OF PURPOSE

SEC. 600. [291] The purpose of this title is—

(a) to assist the several States in the carrying out of their programs for the construction and modernization of such public or other nonprofit community hospitals and other medical facilities as may be necessary, in conjunction with existing facilities, to furnish adequate hospital, clinic, or similar services to all their people;

(b) to stimulate the development of new or improved types of physical facilities for medical, diagnostic, preventive, treatment, or rehabilitative services; and

(c) to promote research, experiments, and demonstrations relating to the effective development and utilization of hospital, clinic, or similar services, facilities, and resources, and to promote the coordination of such research, experiments, and demonstrations and the useful application of their results.

PART A—GRANTS AND LOANS FOR CONSTRUCTION AND MODERNIZATION OF HOSPITALS AND OTHER MEDICAL FACILITIES

AUTHORIZATION OF APPROPRIATIONS FOR CONSTRUCTION AND MODERNIZATION GRANTS

SEC. 601. [291a] In order to assist the States in carrying out the purposes of section 600, there are authorized to be appropriated—

(a) for the fiscal year ending June 30, 1974—

(1) \$20,800,000 for grants for the construction of public or other nonprofit facilities for long-term care;

(2) \$70,000,000 for grants for the construction of public or other nonprofit outpatient facilities;

(3) \$15,000,000 for grants for the construction of public or other nonprofit rehabilitation facilities;

(b) for grants for the construction of public or other nonprofit hospitals and public health centers, \$150,000,000 for the fiscal year ending June 30, 1965, \$160,000,000 for the fiscal year ending June 30, 1966, \$170,000,000 for the fiscal year ending June 30, 1967, \$180,000,000 each for the next two fiscal years, \$195,000,000 for the fiscal year ending June 30, 1970, \$147,500,000 for the fiscal year ending June 30, 1971, \$152,500,000 for the fiscal year ending June 30, 1972, \$157,500,000 for the fiscal year ending June 30, 1973, and \$41,400,000 for the fiscal year ending June 30, 1974; and

(c) for grants for modernization of the facilities referred to in paragraphs (a) and (b), \$65,000,000 for the fiscal year ending June 30, 1971, \$80,000,000 for the fiscal year ending June 30, 1972,

\$90,000,000 for the fiscal year ending June 30, 1973, and \$50,000,000 for the fiscal year ending June 30, 1974.

STATE ALLOTMENTS

SEC. 602. [291b] (a)(1) Each State shall be entitled for each fiscal year to an allotment bearing the same ratio to the sums appropriated for such year pursuant to subparagraphs (1), (2), and (3), respectively, of section 601(a), and to an allotment bearing the same ratio to the sums appropriated for such year pursuant to section 601(b), as the product of—

(A) the population of such State, and

(B) the square of its allotment percentage,

bears to the sum of the corresponding products for all of the States.

(2) For each fiscal year, the Secretary shall, in accordance with regulations, make allotments among the States, from the sums appropriated for such year under section 601(c), on the basis of the population, the financial need, and the extent of the need for modernization of the facilities referred to in paragraphs (a) and (b) of section 601, of the respective States.

(b)(1) The allotment to any State under subsection (a) for any fiscal year which is less than—

(A) \$50,000 for the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam and \$100,000 for any other State, in the case of an allotment for grants for the construction of public or other nonprofit rehabilitation facilities.

(B) \$100,000 for the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam and \$200,000 for any other State in the case of an allotment for grants for the construction of public or other nonprofit outpatient facilities.

(C) \$200,000 for the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam and \$300,000 for any other State in the case of an allotment for grants for the construction of public or other nonprofit facilities for long-term care or for the construction of public or other nonprofit hospitals and public health centers, or for the modernization of facilities referred to in paragraph (a) or (b) of section 601, or

(D) \$200,000 for the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam and \$300,000 for any other State in the case of an allotment for grants for the modernization of facilities referred to in paragraphs (a) and (b) of section 601,

shall be increased to that amount, the total of the increases thereby required being derived by proportionately reducing the allotment from appropriations under such subparagraph or paragraph to each of the remaining States under subsection (a) of this section, but with such adjustments as may be necessary to prevent the allotment of any of such remaining States from appropriations under such subparagraph or paragraph from being thereby reduced to less than that amount.

(2) An allotment of the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam for any fiscal year

may be increased as provided in paragraph (1) only to the extent it satisfies the Surgeon General, at such time prior to the beginning of such year as the Surgeon General may designate, that such increase will be used for payments under and in accordance with the provisions of this part.

(c) For the purposes of this part—

(1) The "allotment percentage" for any State shall be 100 per centum less that percentage which bears the same ratio to 50 per centum as the per capita income of such State bears to the per capita income of the United States, except that (A) the allotment percentage shall in no case be more than 75 per centum or less than $33\frac{1}{3}$ per centum, and (B) the allotment percentage for the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, and the Virgin Islands shall be 75 per centum.

(2) The allotment percentages shall be determined by the Surgeon General between July 1 and September 30 of each even-numbered year, on the basis of the average of the per capita incomes of each of the States and of the United States for the three most recent consecutive years for which satisfactory data are available from the Department of Commerce, and the States shall be notified promptly thereof. Such determination shall be conclusive for each of the two fiscal years in the period beginning July 1 next succeeding such determination.

(3) The population of the several States shall be determined on the basis of the latest figures certified by the Department of Commerce.

(4) The term "United States" means (but only for purposes of paragraphs (1) and (2)) the fifty States and the District of Columbia.

(d)(1) Any sum allotted to a State, other than the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, and Guam for a fiscal year under this section and remaining unobligated at the end of such year shall remain available to such State, for the purpose for which made, for the next two fiscal years (and for such years only), in addition to the sums allotted to such State for such purposes for such next two fiscal years.

(2) Any sum allotted to the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam for a fiscal year under this section and remaining unobligated at the end of such year shall remain available to it, for the purpose for which made, for the next two fiscal years (and for such years only), in addition to the sums allotted to it for such purpose for each of such next two fiscal years.

(e)(1) Upon the request of any State that a specified portion of any allotment of such State under subsection (a) for any fiscal year be added to any other allotment or allotments of such State under such subsection for such year, the Secretary shall promptly (but after application of subsection (b)) adjust the allotments of such State in accordance with such request and shall notify the State agency; except that the aggregate of the portions so transferred from an allotment for a fiscal year pursuant to this paragraph may not exceed the amount specified with respect to such allotment in

clause (A), (B), (C), or (D), as the case may be, of subsection (b)(1) which is applicable to such State.

(2) In addition to the transfer of portions of allotments under paragraph (1), upon the request of any State that a specified portion of any allotment of such State under subsection (a), other than an allotment for grants for the construction of public or other non-profit rehabilitation facilities, be added to another allotment of such State under such subsection, other than an allotment for grants for the construction of public or other nonprofit hospitals and public health centers, and upon simultaneous certification to the Secretary by the State agency in such State to the effect that—

(A) it has afforded a reasonable opportunity to make applications for the portion so specified and there have been no approvable applications for such portions, or

(B) in the case of a request to transfer a portion of an allotment for grants for the construction of public or other non-profit hospitals and public health centers, use of such portion as requested by such State agency will better carry out the purposes of this title,

the Secretary shall promptly (but after application of subsection (b)) adjust the allotments of such State in accordance with such request and shall notify the State agency.

(3) In addition to the transfer of portions of allotments under paragraph (1) or (2), upon the request of any State that a specified portion of an allotment of such State under paragraph (2) of subsection (a) be added to an allotment of such State under paragraph (1) of such subsection for grants for the construction of public or other nonprofit hospitals and public health centers, and upon simultaneous certification by the State agency in such State to the effect that the need for new public or other nonprofit hospitals and public health centers is substantially greater than the need for modernization of facilities referred to in paragraph (a) or (b) of section 601, the Secretary shall promptly (but after application of subsection (b) of this section) adjust the allotments of such State in accordance with such request and shall notify the State agency.

(4) After adjustment of allotments of any State, as provided in paragraph (1), (2), or (3) of this subsection, the allotments as so adjusted shall be deemed to be the State's allotments under this section.

(f) In accordance with regulations, any State may file with the Surgeon General a request that a specified portion of an allotment to it under this part for grants for construction of any type of facility, or for modernization of facilities, be added to the corresponding allotment of another State for the purpose of meeting a portion of the Federal share of the cost of a project for the construction of a facility of that type in such other State, or for modernization of a facility in such other State, as the case may be. If it is found by the Surgeon General (or, in the case of a rehabilitation facility, by the Surgeon General and the Secretary) that construction or modernization of the facility with respect to which the request is made would meet needs of the State making the request and that use of the specified portion of such State's allotment, as requested by it, would assist in carrying out the purposes of this title, such portion of such State's allotment shall be added to the corresponding allot-

ment of the other State, to be used for the purpose referred to above.

GENERAL REGULATIONS

SEC. 603. [291c] The Surgeon General, with the approval of the Federal Hospital Council and the Secretary of Health, Education, and Welfare, shall by general regulations prescribe—

(a) the general manner in which the State agency shall determine the priority of projects based on the relative need of different areas lacking adequate facilities of various types for which assistance is available under this part, giving special consideration—

(1) in the case of projects for the construction of hospitals, to facilities serving areas with relatively small financial resources and, at the option of the State, rural communities;

(2) in the case of projects for the construction of rehabilitation facilities, to facilities operated in connection with a university teaching hospital which will provide an integrated program of medical, psychological, social, and vocational evaluation and services under competent supervision;

(3) in the case of projects for modernization of facilities, to facilities serving densely populated areas;

(4) in the case of projects for construction or modernization of outpatient facilities, to any outpatient facility that will be located in, and provide services for residents of, an area determined by the Secretary to be a rural or urban poverty area;

(5) to projects for facilities which, alone or in conjunction with other facilities, will provide comprehensive health care, including outpatient and preventive care as well as hospitalization;

(6) to facilities which will provide training in health or allied health professions; and

(7) to facilities which will provide to a significant extent, for the treatment of alcoholism;

(b) general standards of construction and equipment for facilities of different classes and in different types of location, for which assistance is available under this part;

(c) criteria for determining needs for general hospital and long-term care beds, and needs for hospitals and other facilities for which aid under this part is available, and for developing plans for the distribution of such beds and facilities;

(d) criteria for determining the extent to which existing facilities, for which aid under this part is available, are in need of modernization; and

(e) that the State plan shall provide for adequate hospitals, and other facilities for which aid under this part is available, for all persons residing in the State, and adequate hospitals (and such other facilities) to furnish needed services for persons unable to pay therefor. Such regulations may also require that before approval of an application for a project is recommended by a State agency to the Surgeon General for approval under this part, assurance shall be received by the State from the applicant that (1) the facility or portion thereof to be constructed or modernized will be made available to all persons residing in the territorial area of the applicant;

and (2) there will be made available in the facility or portion thereof to be constructed or modernized a reasonable volume of services to persons unable to pay therefor, but an exception shall be made if such a requirement is not feasible from a financial viewpoint.

STATE PLANS

SEC. 604. [291d] (a) Any State desiring to participate in this part may submit a State plan. Such plan must—

(1) designate a single State agency as the sole agency for the administration of the plan, or designate such agency as the sole agency for supervising the administration of the plan;

(2) contain satisfactory evidence that the State agency designated in accordance with paragraph (1) will have authority to carry out such plan in conformity with this part;

(3) provide for the designation of a State advisory council which shall include (A) representatives of nongovernmental organizations or groups, and of public agencies, concerned with the operation, construction, or utilization of hospital or other facilities for diagnosis, prevention, or treatment of illness or disease, or for provision of rehabilitation services, and representatives particularly concerned with education or training of health professions personnel, and (B) an equal number of representatives of consumers familiar with the need for the services provided by such facilities, to consult with the State agency in carrying out the plan, and provide, if such council does not include any representatives of nongovernmental organizations or groups, or State agencies, concerned with rehabilitation, for consultation with organizations, groups, and State agencies so concerned;

(4) set forth, in accordance with criteria established in regulations prescribed under section 603 and on the basis of a statewide inventory of existing facilities, a survey of need, and (except to the extent provided by or pursuant to such regulations) community, area, or regional plans—

(A) the number of general hospital beds and long-term care beds, and the number and types of hospital facilities and facilities for long-term care, needed to provide adequate facilities for inpatient care of people residing in the State, and a plan for the distribution of such beds and facilities in service areas throughout the State;

(B) the public health centers needed to provide adequate public health services for people residing in the State, and a plan for the distribution of such centers throughout the State;

(C) the outpatient facilities needed to provide adequate diagnostic or treatment services to ambulatory patients residing in the State, and a plan for distribution of such facilities throughout the State;

(D) the rehabilitation facilities needed to assure adequate rehabilitation services for disabled persons residing in the State, and a plan for distribution of such facilities throughout the State; and

(E) effective January 1, 1966, the extent to which existing facilities referred to in section 601 (a) or (b) in the State are in need of modernization;

(5) set forth a construction and modernization program conforming to the provisions set forth pursuant to paragraph (4) and regulations prescribed under section 603 and providing for construction or modernization of the hospital or long-term care facilities, public health centers, outpatient facilities and rehabilitation facilities which are needed, as determined under the provisions so set forth pursuant to paragraph (4);

(6) set forth, with respect to each of such types of medical facilities, the relative need, determined in accordance with regulations prescribed under section 603, for projects for facilities of that type, and provide for the construction or modernization, insofar as financial resources available therefor and for maintenance and operation make possible, in the order of such relative need;

(7) provide minimum standards (to be fixed in the discretion of the State) for the maintenance and operation of facilities providing inpatient care which receive aid under this part and, effective July 1, 1966, provide for enforcement of such standards with respect to projects approved by the Surgeon General under this part after June 30, 1964;

(8) provide such methods of administration of the State plan, including methods relating to the establishment and maintenance of personnel standards on a merit basis (except that the Surgeon General shall exercise no authority with respect to the selection, tenure of office, or compensation of any individual employed in accordance with such methods), as are found by the Surgeon General to be necessary for the proper and efficient operation of the plan;

(9) provide for affording to every applicant for a construction or modernization project an opportunity for a hearing before the State agency;

(10) provide that the State agency will make such reports, in such form and containing such information, as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports;

(11) provide that the Comptroller General of the United States or his duly authorized representatives shall have access for the purpose of audit and examination to the records specified in paragraph (10);

(12) provide that the State agency will from time to time, but not less often than annually, review its State plan and submit to the Surgeon General any modifications thereof which it considers necessary; and

(13) effective July 1, 1971, provide that before any project for construction or modernization of any general hospital is approved by the State agency there will be reasonable assurance of adequate provision for extended care services (as determined in accordance with regulations) to patients of such hospital when such services are medically appropriate for them, with

such services being provided in facilities which (A) are structurally part of, physically connected with, or in immediate proximity to, such hospital, and (B) either (i) are under the supervision of the professional staff of such hospital or (ii) have organized medical staffs and have in effect transfer agreements with such hospital; except that the Secretary may, at the request of the State agency, waive compliance with clause (A) or (B), or both such clauses, as the case may be, in the case of any project if the State agency has determined that compliance with such clause or clauses in such case would be inadvisable.

(b) The Surgeon General shall approve any State plan and any modification thereof which complies with the provisions of subsection (a). If any such plan or modification thereof shall have been disapproved by the Surgeon General for failure to comply with subsection (a), the Federal Hospital Council shall, upon request of the State agency, afford it an opportunity for hearing. If such Council determines that the plan or modification complies with the provisions of such subsection, the Surgeon General shall thereupon approve such plan or modification.

APPROVAL OF PROJECTS FOR CONSTRUCTION OR MODERNIZATION

SEC. 605. [291e] (a) For each project pursuant to a State plan approved under this part, there shall be submitted to the Surgeon General, through the State agency, an application by the State or a political subdivision thereof or by a public or other nonprofit agency. If two or more such agencies join in the project, the application may be filed by one or more of such agencies. Such application shall set forth—

- (1) a description of the site for such project;
- (2) plans and specifications therefor, in accordance with regulations prescribed under section 603;
- (3) reasonable assurance that title to such site is or will be vested on one or more of the agencies filing the application or in a public or other nonprofit agency which is to operate the facility on completion of the project;
- (4) reasonable assurance that adequate financial support will be available for the completion of the project and for its maintenance and operation when completed;
- (5) reasonable assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of construction or modernization on the project will be paid wages at rates not less than those prevailing on similar work in the locality as determined by the Secretary of Labor in accordance with the Davis-Bacon Act, as amended (40 U.S.C. 276a—276a-5); and the Secretary of Labor shall have with respect to the labor standards specified in this paragraph the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 F.R. 3176; 5 U.S.C. 133z-15) and section 2 of the Act of June 13, 1934, as amended (40 U.S.C. 276c); and

(6) a certification by the State agency of the Federal share for the project.

(b) The Surgeon General shall approve such application if sufficient funds to pay the Federal share of the cost of such project are

available from the appropriate allotment to the State, and if the Surgeon General finds (1) that the application contains such reasonable assurance as to title, financial support, and payment of prevailing rates of wages; (2) that the plans and specifications are in accord with the regulations prescribed pursuant to section 603; (3) that the application is in conformity with the State plan approved under section 604 and contains an assurance that in the operation of the project there will be compliance with the applicable requirements of the regulations prescribed under section 603(e), and with State standards for operation and maintenance; and (4) that the application has been approved and recommended by the State agency, opportunity has been provided, prior to such approval and recommendation, for consideration of the project by the public or nonprofit private agency or organization which has developed the comprehensive regional, metropolitan area, or other local area plan or plans referred to in section 314(b) covering the area in which such project is to be located or, if there is no such agency or organization, by the State agency administering or supervising the administration of the State plan approved under section 314(a), and the application is for a project which is entitled to priority over other projects within the State in accordance with the regulations prescribed pursuant to section 603(a). Notwithstanding the preceding sentence, the Surgeon General may approve such an application for a project for construction or modernization of a rehabilitation facility only if it is also approved by the Secretary of Health, Education, and Welfare.

(c) No application shall be disapproved until the Surgeon General has afforded the State agency an opportunity for a hearing.

(d) Amendment of any approved application shall be subject to approval in the same manner as an original application.

(e) Notwithstanding any other provision of this title, no application for an outpatient facility shall be approved under this section unless the applicant is (1) a State, political subdivision, or public agency, or (2) a corporation or association which owns and operates a nonprofit hospital (as defined in section 645) or which provides reasonable assurance that the services of a general hospital will be available to patients of such facility who are in need of hospital care.

PAYMENTS FOR CONSTRUCTION OR MODERNIZATION

SEC. 606. [291f] (a) Upon certification to the Surgeon General by the State agency, based upon inspection by it, that work has been performed upon a project, or purchases have been made, in accordance with the approved plans and specifications, and that payment of an installment is due to the applicant, such installment shall be paid to the State, from the applicable allotment of such State, except that (1) if the State is not authorized by law to make payments to the applicant, or if the State so requests, the payment shall be made directly to the applicant, (2) if the Surgeon General, after investigation or otherwise, has reason to believe that any act (or failure to act) has occurred requiring action pursuant to section 607, payment may, after he has given the State agency notice of opportunity for hearing pursuant to such section, be withheld, in whole or in part, pending corrective action or action based on such

hearing, and (3) the total of payments under this subsection with respect to such project may not exceed an amount equal to the Federal share of the cost of construction of such project.

(b) In case an amendment to an approved application is approved as provided in section 605 or the estimated cost of a project is revised upward, any additional payment with respect thereto may be made from the applicable allotment of the State for the fiscal year in which such amendment or revision is approved.

(c)(1) At the request of any State, a portion of any allotment or allotments of such State under this part shall be available to pay one-half (or such smaller share as the State may request) of the expenditures found necessary by the Surgeon General for the proper and efficient administration during such year of the State plan approved under this part; except that not more than 4 per centum of the total of the allotments of such State for a year, or \$100,000, whichever is less, shall be available for such purpose for such year. Payments of amounts due under this paragraph may be made in advance or by way of reimbursement, and in such installments, as the Surgeon General may determine.

(2) Any amount paid under paragraph (1) to any State for any fiscal year shall be paid on condition that there shall be expended from State sources for such year for administration of the State plan approved under this part not less than the total amount expended for such purposes from such sources during the fiscal year ending June 30, 1970.

WITHHOLDING OF PAYMENTS

SEC. 607. [291g] Whenever the Surgeon General, after reasonable notice and opportunity for hearing to the State agency designated as provided in section 604(a)(1), finds—

(a) that the State agency is not complying substantially with the provisions required by section 604 to be included in its State plan; or

(b) that any assurance required to be given in an application filed under section 605 is not being or cannot be carried out; or

(c) that there is a substantial failure to carry out plans and specifications approved by the Surgeon General under section 605; or

(d) that adequate State funds are not being provided annually for the direct administration of the State plan,

the Surgeon General may forthwith notify the State agency that—

(e) no further payments will be made to the State under this part, or

(f) no further payments will be made from the allotments of such State from appropriations under any one or more subparagraphs or paragraphs of section 601, or for any project or projects, designated by the Surgeon General as being affected by the action or inaction referred to in paragraph (a), (b), (c), or (d) of this section, as the Surgeon General may determine to be appropriate under the circumstances; and, except with regard to any project for which the application has already been approved and which is not directly affected, further payments may be withheld, in whole or in part, until there is no longer

any failure to comply (or carry out the assurance or plans and specifications or provide adequate State funds, as the case may be) or, if such compliance (or other action) is impossible, until the State repays or arranges for the repayment of Federal moneys to which the recipient was not entitled.

JUDICIAL REVIEW

SEC. 608. [291h] (a) If the Surgeon General refuses to approve any application for a project submitted under section 605 or section 610, the State agency through which such application was submitted, or if any State is dissatisfied with his action under section 607 such State may appeal to the United States court of appeals for the circuit in which such State is located, by filing a petition with such court within sixty days after such action. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Surgeon General, or any officer designated by him for that purpose. The Surgeon General shall thereupon file in the court the record of the proceedings on which he based his action, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have jurisdiction to affirm the action of the Surgeon General or to set it aside, in whole or in part, temporarily or permanently, but until the filing of the record, the Surgeon General may modify or set aside his order.

(b) The findings of the Surgeon General as to the facts, if supported by substantial evidence, shall be conclusive, but the court, for good cause shown, may remand the case to the Surgeon General to take further evidence, and the Surgeon General may thereupon make new or modified findings of fact and may modify his previous action, and shall file in the court the record of the further proceedings. Such new or modified findings of fact shall likewise be conclusive if supported by substantial evidence.

(c) The judgment of the court affirming or setting aside, in whole or in part, any action of the Surgeon General shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28, United States Code. The commencement of proceedings under this section shall not, unless so specifically ordered by the court, operate as a stay of the Surgeon General's action.

RECOVERY

SEC. 609.¹ [291i] (a) If any facility with respect to which funds have been paid under section 606 shall, at any time within 20 years after the completion of construction or modernization—

(1) be sold or transferred to any entity (A) which is not qualified to file an application under section 605, or (B) which is not approved as a transferee by the State agency designated pursuant to section 604, or its successor, or

¹Subtitle D of title VII of Public Law 100-607 waived the applicability of section 609 regarding a specified medical facility if certain conditions relating to satisfaction of the obligations under section 603(e) were met. (The text of such subtitle D is provided in this compilation under the heading "Waiver Regarding Title VI of Public Health Service Act".) Private Law 99-21 provided such a waiver regarding another specified medical facility.

(2) cease to be a public health center or a public or other nonprofit hospital, outpatient facility, facility for long-term care, or rehabilitation facility, the United States shall be entitled to recover, whether from the transferor or the transferee (or, in the case of a facility which has ceased to be public or nonprofit, from the owners thereof) an amount determined under subsection (c).

(b) The transferor of a facility which is sold or transferred as described in subsection (a)(1), or the owner of a facility the use of which is changed as described in subsection (a)(2), shall provide the Secretary written notice of such sale, transfer, or change not later than the expiration of 10 days from the date on which such sale, transfer, or change occurs.

(c)(1) except as provided in paragraph (2), the amount the United States shall be entitled to recover under subsection (a) is an amount bearing the same ratio to the then value (as determined by the agreement of the parties or in an action brought in the district court of the United States for the district for which the facility involved is situated) of so much of the facility as constituted an approved project or projects as the amount of the Federal participation bore to the cost of the construction or modernization of such project or projects.

(2)(A) After the expiration of—

(i) 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b), in the case of a facility which is sold or transferred or the use of which changes after the date of the enactment of this subsection, or

(ii) thirty days after the date of the enactment of this subsection or if later 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b), in the case of a facility which was sold or transferred or the use of which changed before the date of the enactment of this subsection.

the amount which the United States is entitled to recover under paragraph (1) with respect to a facility shall be the amount prescribed by paragraph (1) plus interest, during the period described in subparagraph (B), at a rate (determined by the Secretary) based on the average of the bond equivalent of the weekly ninety-day Treasury bill auction rate.

(B) The period referred to in subparagraph (A) is the period beginning—

(i) in the case of a facility which was sold or transferred or the use of which changed before the date of the enactment of this subsection, thirty days after such date or if later 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b),

(ii) in the case of a facility with respect to which notice is provided in accordance with subsection (b), upon the expiration of 180 days after the receipt of such notice, or

(iii) in the case of a facility with respect to which such notice is not provided as prescribed by subsection (b), on the date of the sale, transfer, or change of use for which such notice was to be provided,

and ending on the date the amount the United States is entitled to under paragraph (1) is collected.

(d)(1) The Secretary may waive the recovery rights of the United States under subsection (a)(1) with respect to a facility in any State if the Secretary determines, in accordance with regulations, that the entity to which the facility was sold or transferred—

(A) has established an irrevocable trust—

(i) in an amount equal to the greater of twice the cost of the remaining obligation of the facility under clause (2) of section 603(e) or the amount, determined under subsection (c), that the United States is entitled to recover, and

(ii) which will only be used by the entity to provide the care required by clause (2) of section 603(e); and

(B) will meet the obligation of the facility under clause (1) of section 603(e).

(2) The Secretary may waive the recovery rights of the United States under subsection (a)(2) with respect to a facility in any State if the Secretary determines, in accordance with regulations, that there is good cause for waiving such rights with respect to such facility.

(e) The right of recovery of the United States under subsection (a) shall not constitute a lien on any facility with respect to which funds have been paid under section 606.

LOANS FOR CONSTRUCTION OR MODERNIZATION OF HOSPITALS AND OTHER MEDICAL FACILITIES

SEC. 610. [291j] (a) In order further to assist the States in carrying out the purposes of this title, the Surgeon General is authorized to make a loan of funds to the applicant for any project for construction or modernization which meets all of the conditions specified for a grant under this part.

(b) Except as provided in this section, an application for a loan with respect to any project under this part shall be submitted, and shall be approved by the Surgeon General, in accordance with the same procedures and subject to the same limitations and conditions as would be applicable to the making of a grant under this part for such project. Any such application may be approved in any fiscal year only if sufficient funds are available from the allotment for the type of project involved. All loans under this section shall be paid directly to the applicant.

(c)(1) The amount of a loan under this part shall not exceed an amount equal to the Federal share of the estimated cost of construction or modernization under the project. Where a loan and a grant are made under this part with respect to the same project, the aggregate amount of such loan and such grant shall not exceed an amount equal to the Federal share of the estimated cost of construction or modernization under the project. Each loan shall bear interest at the rate arrived at by adding one-quarter of 1 per centum per annum to the rate which the Secretary of the Treasury determines to be equal to the current average yield on all outstanding marketable obligations of the United States as of the last day of the month preceding the date the application for the loan is ap-

proved and by adjusting the result so obtained to the nearest one-eighth of 1 per centum. Each loan made under this part shall mature not more than forty years after the date on which such loan is made, except that nothing in this part shall prohibit the payment of all or part of the loan at any time prior to the maturity date. In addition to the terms and conditions provided for, each loan under this part shall be made subject to such terms, conditions, and covenants relating to repayment of principal, payment of interest, and other matters as may be agreed upon by the applicant and the Surgeon General.

(2) The Surgeon General may enter into agreements modifying any of the terms and conditions of a loan made under this part whenever he determines such action is necessary to protect the financial interest of the United States.

(3) If, at any time before a loan for a project has been repaid in full, any of the events specified in clause (a) or clause (b) of section 609 occurs with respect to such project, the unpaid balance of the loan shall become immediately due and payable by the applicant, and any transferee of the facility shall be liable to the United States for such repayment.

(d) Any loan under this part shall be made out of the allotment from which a grant for the project concerned would be made. Payments of interest and repayments of principal on loans under this part shall be deposited in the Treasury as miscellaneous receipts.

PART B—LOAN GUARANTEES AND LOANS FOR MODERNIZATION AND CONSTRUCTION OF HOSPITALS AND OTHER MEDICAL FACILITIES

AUTHORIZATION OF LOAN GUARANTEES AND LOANS

SEC. 621. [291j-1] (a)(1) In order to assist nonprofit private agencies to carry out needed projects for the modernization or construction of nonprofit private hospitals, facilities for long-term care, outpatient facilities, and rehabilitation facilities, the Secretary, during the period July 1, 1970, through June 30, 1974, may, in accordance with the provisions of this part, guarantee to non-Federal lenders making loans to such agencies for such projects, payment of principal of and interest on loans, made by such lenders, which are approved under this part.

(2) In order to assist public agencies to carry out needed projects for the modernization or construction of public health centers, and public hospitals, facilities for long-term care, outpatient facilities, and rehabilitation facilities, the Secretary, during the period July 1, 1970, through June 30, 1974, may, in accordance with the provisions of this part, make loans to such agencies which shall be sold and guaranteed in accordance with section 627.

(b)(1) No loan guarantee under this part with respect to any modernization or construction project may apply to so much of the principal amount thereof as, when added to the amount of any grant or loan under part A with respect to such project, exceeds 90 per centum of the cost of such project.

(2) No loan to a public agency under this part shall be made in an amount which, when added to the amount of any grant or loan under part A with respect to such project, exceeds 90 per centum of the cost of such project.

(c) The Secretary, with the consent of the Secretary of Housing and Urban Development, shall obtain from the Department of Housing and Urban Development such assistance with respect to the administration of this part as will promote efficiency and economy thereof.

ALLOCATION AMONG THE STATES

SEC. 622. [291j-2] (a) For each fiscal year, the total amount of principal of loans to nonprofit private agencies which may be guaranteed or loans to public agencies which may be directly made under this part shall be allotted by the Secretary among the States, in accordance with regulations, on the basis of each State's relative population, financial need, need for construction of the facilities referred to in section 621(a), and need for modernization of such facilities.

(b) Any amount allotted under subsection (a) to a State for a fiscal year ending before July 1, 1973, and remaining unobligated at the end of such year shall remain available to such State, for the purpose for which made, for the next two fiscal years (and for such years only), and any such amount shall be in addition to the amounts allotted to such State for such purpose for each of such next two fiscal years; except that, with the consent of any such State, any such amount remaining unobligated at the end of the first of such next fiscal year may be reallocated (on such basis as the Secretary deems equitable and consistent with the purposes of this title) to other States which have need therefor. Any amounts so reallocated to a State shall be available for the purposes for which made until the close of the second such next two fiscal years and shall be in addition to the amount allotted and available to such State for the same period.

(c) Any amount allotted or reallocated to a State under this section for a fiscal year shall not, until the expiration of the period during which it is available for obligation, be considered as available for allotment for a subsequent fiscal year.

(d) The allotments of any State under subsection (a) for the fiscal year ending June 30, 1971, and the succeeding fiscal year shall also be available to guarantee loans with respect to any project, for modernization or construction of a nonprofit private hospital or other health facility referred to in section 621(a)(1), if the modernization or construction of such facility was not commenced earlier than January 1, 1968, and if the State certifies and the Secretary finds that without such guaranteed loan such facility could not be completed and begin to operate or could not continue to operate, but with such guaranteed loan would be able to do so: *Provided*, That this subsection shall not apply to more than two projects in any one State.

APPLICATIONS AND CONDITIONS

SEC. 623. [291j-3] (a) For each project for which a guarantee of a loan to a nonprofit private agency or a direct loan to a public agency is sought under this part, there shall be submitted to the Secretary, through the State agency designated in accordance with section 604, an application by such private nonprofit agency or by

such public agency. If two or more private nonprofit agencies, or two or more public agencies, join in the project, the application may be filed by one or more such agencies. Such application shall (1) set forth all of the descriptions, plans, specifications, assurances, and information which are required by the third sentence of section 605(a) (other than clause (6) thereof) with respect to applications submitted under that section, (2) contain such other information as the Secretary may require to carry out the purposes of this part, and (3) include a certification by the State agency of the total cost of the project and the amount of the loan for which a guarantee is sought under this part, or the amount of the direct loan sought under this part, as the case may be.

(b) The Secretary may approve such application only if—

(1) there remains sufficient balance in the allotment determined for such State pursuant to section 622 to cover the amount of the loan for which a guarantee is sought, or the amount of the direct loan sought (as the case may be), in such application,

(2) he makes each of the findings which are required by clauses (1) through (4) of section 605(b) for the approval of applications for projects thereunder (except that, in the case of the finding required under such clause (4) of entitlement of a project to a priority established under section 603(a), such finding shall be made without regard to the provisions of clauses (1) and (3) of such section),

(3) he finds that there is compliance with section 605(e),

(4) he obtains assurances that the applicant will keep such records, and afford such access thereto, and make such reports, in such form and containing such information, as the Secretary may reasonably require, and

(5) he also determines, in the case of a loan for which a guarantee is sought, that the terms, conditions, maturity, security (if any), and schedule and amounts of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable and in accord with regulations, including a determination that the rate of interest does not exceed such per centum per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for similar loans and the risks assumed by the United States.

(c) No application under this section shall be disapproved until the Secretary has afforded the State agency an opportunity for a hearing.

(d) Amendment of an approved application shall be subject to approval in the same manner as an original application.

(e)(1) In the case of any loan to a nonprofit private agency, the United States shall be entitled to recover from the applicant the amount of any payments made pursuant to any guarantee of such loan under this part, unless the Secretary for good cause waives its right of recovery, and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

(2) Guarantees of loans to nonprofit private agencies under this part shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this part will be achieved, and, to the extent permitted by subsection (f), any of such terms and conditions may be modified by the Secretary to the extent he determines it to be consistent with the financial interest of the United States.

(f) Any guarantee of a loan to a nonprofit private agency made by the Secretary pursuant to this part shall be incontestable in the hands of an applicant on whose behalf such guarantee is made, and as to any person who makes or contracts to make a loan to such applicant in reliance thereon, except for fraud or misrepresentation on the part of such applicant or such other person.

PAYMENT OF INTEREST ON GUARANTEED LOAN

SEC. 624. [291j-4] (a) Subject to the provisions of subsection (b), in the case of a guarantee of any loan to a nonprofit private agency under this part with respect to a hospital or other medical facility, the Secretary shall pay, to the holder of such loan and for and on behalf of such hospital or other medical facility amounts sufficient to reduce by 3 per centum per annum the net effective interest rate otherwise payable on such loan. Each holder of a loan, to a nonprofit private agency, which is guaranteed under this part shall have a contractual right to receive from the United States interest payments required by the preceding sentence.

(b) Contracts to make the payments provided for in this section shall not carry an aggregate amount greater than such amount as may be provided in appropriations Acts.

LIMITATION ON AMOUNT OF LOANS GUARANTEED OR DIRECTLY MADE

SEC. 625. [291j-5] The cumulative total of the principal of the loans outstanding at any time with respect to which guarantees have been issued, or which have been directly made, under this part may not exceed the lesser of—

(1) such limitations as may be specified in appropriations Acts, or

(2) in the case of loans covered by allotments for the fiscal year ending June 30, 1971, \$500,000,000; for the fiscal year ending June 30, 1972, \$1,000,000,000; and for each of the fiscal years ending June 30, 1973, and June 30, 1974.

LOAN GUARANTEE AND LOAN FUND

SEC. 626. [291j-6] (a)(1) There is hereby established in the Treasury a loan guarantee and loan fund (hereinafter in this section referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriations Acts, (i) to enable him to discharge his responsibilities under guarantees issued by him under this part, (ii) for payment of interest on the loans to nonprofit agencies which are guaranteed, (iii) for direct loans to public agencies which are sold and guaranteed, (iv) for payment of interest with respect to such loans, and (v) for repurchase by him of direct loans to public agencies which have been sold and guaranteed.

There are authorized to be appropriated to the fund from time to time such amounts as may be necessary to provide capital required for the fund. To the extent authorized from time to time in appropriation Acts, there shall be deposited in the fund amounts received by the Secretary as interest payments or repayments of principal on loans and any other moneys, property, or assets derived by him from his operations under this part, including any moneys derived from the sale of assets.

(2) Of the moneys in the fund, there shall be available to the Secretary for the purpose of making of direct loans to public agencies only such sums as shall have been appropriated for such purpose pursuant to section 627 or sums received by the Secretary from the sale of such loans (in accordance with such section) and authorized in appropriations Acts to be used for such purpose.

(b) If at any time the moneys in the fund are insufficient to enable the Secretary to discharge his responsibilities under this part—

(i) to make payments of interest on loans to nonprofit private agencies which he has guaranteed under this part;

(ii) to otherwise comply with guarantees under this part of loans to nonprofit private agencies;

(iii) to make payments of interest subsidies with respect to loans to public agencies which he has made, sold, and guaranteed under this part;

(iv) in the event of default by public agencies to make payments of principal and interest on loans which the Secretary has made, sold, and guaranteed, under this part, to make such payments to the purchaser of such loan;

(v) to repurchase loans to public agencies which have been sold and guaranteed under this part,

he is authorized to issue to the Secretary of the Treasury notes or other obligations in such forms and denominations, bearing such maturities, and subject to such terms and conditions, as may be prescribed by the Secretary with the approval of the Secretary of the Treasury, but only in such amounts as may be specified from time to time in appropriations Acts. Such notes or other obligations shall bear interest at a rate determined by the Secretary of the Treasury, taking into consideration the current average market yield on outstanding marketable obligations of the United States of comparable maturities during the month preceding the issuance of the notes or other obligations. The Secretary of the Treasury is authorized and directed to purchase any notes and other obligations issued hereunder and for that purpose he is authorized to use as a public debt transaction the proceeds from the sale of any securities issued under the Second Liberty Bond Act, as amended, and the purposes for which securities may be issued under that Act, as amended, are extended to include any purchase of such notes and obligations. The Secretary of the Treasury may at any time sell any of the notes or other obligations acquired by him under this subsection. All redemptions, purchases, and sales by the Secretary of the Treasury of such notes or other obligations shall be treated as public debt transactions of the United States. Sums borrowed under this subsection shall be deposited in the fund and redemp-

tion of such notes and obligations shall be made by the Secretary from such fund.

PROVISIONS APPLICABLE TO LOANS TO PUBLIC FACILITIES

SEC. 627. [291j-7] (a)(1) Any loan made by the Secretary to a public agency under this part for the modernization or construction of a public hospital or other health facility shall require such public agency to pay interest thereon at a rate comparable to the current rate of interest prevailing with respect to loans, to non-profit private agencies, which are guaranteed under this part, for the modernization or construction of similar facilities in the same or similar areas, minus 3 per centum per annum.

(2)(A) No loan to a public agency shall be made under this part unless—

(i) the Secretary is reasonably satisfied that such agency will be able to make payments of principal and interest thereon when due, and

(ii) such agency provides the Secretary with reasonable assurances that there will be available to such agency such additional funds as may be necessary to complete the project with respect to which such loan is requested.

(B) Any loan to a public agency shall have such security, have such maturity date, be repayable in such installments, and be subject to such other terms and conditions (including provision for recovery in case of default) as the Secretary determines to be necessary to carry out the purposes of this part while adequately protecting the financial interests of the United States.

(3) In making loans to public agencies under this part, the Secretary shall give due regard to achieving an equitable geographical distribution of such loans.

(b)(1) The Secretary shall from time to time, but with due regard to the financial interests of the United States, sell loans referred to in subsection (a)(1) either on the private market or to the Federal National Mortgage Association in accordance with section 302 of the Federal National Mortgage Association Charter Act.

(2) Any loan so sold shall be sold for an amount which is equal (or approximately equal) to the amount of the unpaid principal of such loan as of the time of sale.

(c)(1) The Secretary is authorized to enter into an agreement with the purchaser of any loan sold under this part under which the Secretary agrees—

(A) to guarantee to such purchaser (and any successor in interest to such purchaser) payments of the principal and interest payable under such loan, and

(B) to pay as an interest subsidy to such purchaser (and any successor in interest of such purchaser) amounts which when added to the amount of interest payable on such loan, are equivalent to a reasonable rate of interest on such loan as determined by the Secretary, after taking into account the range of prevailing interest rates in the private market on similar loans and the risks assumed by the United States.

(2) Any such agreement—

(A) may provide that the Secretary shall act as agent of any such purchaser, for the purpose of collecting from the public agency to which such loan was made and paying over to such purchaser, any payments of principal and interest payable by such agency under such loan;

(B) may provide for the repurchase by the Secretary of any such loan on such terms and conditions as may be specified in the agreement;

(C) shall provide that, in the event of any default by the public agency to which such loan was made in payment of principal and interest due on such loan, the Secretary shall, upon notification to the purchaser (or to the successor in interest of such purchaser), have the option to close out such loan (and any obligations of the Secretary with respect thereto) by paying to the purchaser (or his successor in interest) the total amount of outstanding principal and interest due thereon at the time of such notification; and

(D) shall provide that, in the event such loan is closed out as provided in subparagraph (C), or in the event of any other loss incurred by the Secretary by reason of the failure of such public agency to make payments of principal and interest on such loan, the Secretary shall be subrogated to all rights of such purchaser for recovery of such loss from such public agency.

(d) The Secretary may, for good cause, waive any right of recovery which he has against a public agency by reason of the failure of such agency to make payments of principal and interest on a loan made to such agency under this part.

(e) After any loan to a public agency under this part has been sold and guaranteed, interest paid on such loan and any interest subsidy paid by the Secretary with respect to such loan which is received by the purchaser thereof (or his successor in interest) shall be included in gross income for the purposes of chapter 1 of the Internal Revenue Code of 1954.

(f) Amounts received by the Secretary as proceeds from the sale of loans under this section shall be deposited in the loan fund established by section 626, and shall be available to the Secretary for the making of further loans under this part in accordance with the provisions of subsection (a)(2) of such section.

(g) There is authorized to be appropriated to the Secretary, for deposit in the loan fund established by section 626, \$30,000,000 to provide initial capital for the making of direct loans by the Secretary to public agencies for the modernization or construction of facilities referred to in subsection (a)(1).

PART C—CONSTRUCTION OR MODERNIZATION OF EMERGENCY ROOMS

AUTHORIZATION

SEC. 631. [291j-8] In order to assist in the provision of adequate emergency room service in various communities of the Nation for treatment of accident victims and handling of other medical emergencies through special project grants for the construction or modernization of emergency rooms of general hospitals, there

are authorized to be appropriated \$20,000,000 each for the fiscal year ending June 30, 1971, and the next two fiscal years.

ELIGIBILITY FOR GRANTS

SEC. 632. [291j-9] Funds appropriated pursuant to section 631 shall be available for grants by the Secretary for not to exceed 50 per centum of the cost of construction or modernization of emergency rooms of public or nonprofit general hospitals, including provision or replacement of medical transportation facilities. Such grants shall be made by the Secretary only after consultation with the State agency designated in accordance with section 604(a)(1) of the Public Health Service Act. In order to be eligible for a grant under this part, the project, and the applicant therefor, must meet such criteria as may be prescribed by regulations. Such regulations shall be so designed as to provide aid only with respect to projects for which adequate assistance is not readily available from other Federal, State, local, or other sources, and to assist in providing modern, efficient, and effective emergency room service needed to care for victims of highway, industrial, agricultural, or other accidents and to handle other medical emergencies, and to assist in providing such service in geographical areas which have special need therefor.

PAYMENTS

SEC. 633. [291j-10] Grants under this part shall be paid in advance or by way of reimbursement, in such installments and on such conditions, as in the judgment of the Secretary will best carry out the purposes of this part.

PART D—GENERAL

FEDERAL HOSPITAL COUNCIL AND ADVISORY COMMITTEES

SEC. 641. [291k] (a) In administering this title, the Surgeon General shall consult with a Federal Hospital Council consisting of the Surgeon General, who shall serve as Chairman ex officio, and twelve members appointed by the Secretary of Health, Education, and Welfare. Six of the twelve appointed members shall be persons who are outstanding in fields pertaining to medical facility and health activities, and three of these six shall be authorities in matters relating to the operation of hospitals or other medical facilities, one of them shall be an authority in matters relating to the mentally retarded, and one of them shall be an authority in matters relating to mental health, and the other six members shall be appointed to represent the consumers of services provided by such facilities and shall be persons familiar with the need for such services in urban or rural areas.

(b) Each appointed member shall hold office for a term of four years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term. An appointed member shall not be eligible to serve continuously for more than two terms (whether beginning before or after enactment

of this section) but shall be eligible for reappointment if he has not served immediately preceding his reappointment.

(c) The Council shall meet as frequently as the Surgeon General deems necessary, but not less than once each year. Upon request by three or more members, it shall be the duty of the Surgeon General to call a meeting of the Council.

(d) The Council is authorized to appoint such special advisory or technical committees as may be useful in carrying out its functions.

CONFERENCE OF STATE AGENCIES

SEC. 642. [2911] Whenever in his opinion the purposes of this title would be promoted by a conference, the Surgeon General may invite representatives of as many State agencies, designated in accordance with section 604, to confer as he deems necessary or proper. A conference of the representatives of all such State agencies shall be called annually by the Surgeon General. Upon the application of five or more of such State agencies, it shall be the duty of the Surgeon General to call a conference of representatives of all State agencies joining in the request.

STATE CONTROL OF OPERATIONS

SEC. 643. [291m] Except as otherwise specifically provided, nothing in this title shall be construed as conferring on any Federal office or employee the right to exercise any supervision or control over the administration, personnel, maintenance, or operation of any facility with respect to which any funds have been or may be expended under this title.

LOANS FOR CERTAIN HOSPITAL EXPERIMENTATION PROJECTS

SEC. 643A. [291m-1] (a) In order to alleviate hardship on any recipient of a grant under section 636 of this title (as in effect immediately before the enactment of the Hospital and Medical Facilities Amendments of 1964) for a project for the construction of an experimental or demonstration facility having as its specific purpose the application of novel means for the reduction of hospital costs with respect to which there has been a substantial increase in the cost of such construction (over the estimated cost of such project on the basis of which such grant was made) through no fault of such recipient, the Secretary is authorized to make a loan to such recipient not exceeding 66⅔ per centum of such increased costs, as determined by the Secretary, if the Secretary determines that such recipient is unable to obtain such an amount for such purpose from other public or private sources.

(b) Any such loan shall be made only on the basis of an application submitted to the Secretary in such form and containing such information and assurances as he may prescribe.

(c) Each such loan shall bear interest at the rate of 2½ per centum per annum on the unpaid balance thereof and shall be repayable over a period determined by the Secretary to be appropriate, but not exceeding fifty years.

(d) There are hereby authorized to be appropriated \$3,500,000 to carry out the provisions of this section.

DEFINITIONS

SEC. 645.¹ [291o] For the purposes of this title—

(a) The term "State" includes the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Virgin Islands, and the District of Columbia.

(b)(1) The term "Federal share" with respect to any project means the proportion of the cost of such project to be paid by the Federal Government under this title.

(2) With respect to any project in any State for which a grant is made from an allotment from an appropriation under section 601, the Federal share shall be the amount determined by the State agency designated in accordance with section 604, but not more than $66\frac{2}{3}$ per centum or the State's allotment percentage, whichever is the lower, except that, if the State's allotment percentage is lower than 50 per centum, such allotment percentage shall be deemed to be 50 per centum for purposes of this paragraph.

(3) Prior to the approval of the first project in a State during any fiscal year the State agency designated in accordance with section 604 shall give the Secretary written notification of the maximum Federal share established pursuant to paragraph (2) for projects in such State to be approved by the Secretary during such fiscal year and the method for determining the actual Federal share to be paid with respect to such projects; and such maximum Federal share and such method of determination for projects in such State approved during such fiscal year shall not be changed after such approval.

(4) Notwithstanding the provisions of paragraphs (2) and (3) of this subsection, the Federal share shall, at the option of the State agency, be equal to the per centum provided under such paragraphs plus an incentive per centum (which when combined with the per centum provided under such paragraphs shall not exceed 90 per centum) specified by the State agency in the case of (A) projects that will provide services primarily for persons in an area determined by the Secretary to be a rural or urban poverty area, and (B) projects that offer potential for reducing health care costs through shared services among health care facilities, through inter-facility cooperation, or through the construction or modernization of free-standing outpatient facilities.

(c) The term "hospital" includes general, tuberculosis, and other types of hospitals, and related facilities, such as laboratories, outpatient departments, nurses' home facilities, extended care facilities, facilities related to programs for home health services, self-care units, and central service facilities, operated in connection with hospitals, and also includes education or training facilities for health professions personnel operated as an integral part of a hospital, but does not include any hospital furnishing primarily domiciliary care.

(d) The term "public health center" means a publicly owned facility for the provision of public health services, including related

¹Section 644 was repealed by section 3(b) of Public Law 90-174.

publicly owned facilities such as laboratories, clinics, and administrative offices operated in connection with such a facility.

(e) The term "nonprofit" as applied to any facility means a facility which is owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(f) The term "outpatient facility" means a facility (located in or apart from a hospital) for the diagnosis or diagnosis and treatment of ambulatory patients (including ambulatory inpatients)—

(1) which is operated in connection with a hospital, or

(2) in which patient care is under the professional supervision of persons licensed to practice medicine or surgery in the State, or in the case of dental diagnosis or treatment, under the professional supervision of persons licensed to practice dentistry in the State; or

(3) which offers to patients not requiring hospitalization the services of licensed physicians in various medical specialties, and which provides to its patients a reasonably full-range of diagnostic and treatment services.

(g) The term "rehabilitation facility" means a facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of—

(1) medical evaluation and services, and

(2) psychological, social, or vocational evaluation and services, under competent professional supervision, and in the case of which—

(3) the major portion of the required evaluation and services is furnished within the facility; and

(4) either (A) the facility is operated in connection with a hospital, or (B) all medical and related health services are prescribed by, or are under the general direction of, persons licensed to practice medicine or surgery in the State.

(h) The term "facility for long-term care" means a facility (including an extended care facility) providing in-patient care for convalescent or chronic disease patients who require skilled nursing care and related medical services—

(1) which is a hospital (other than a hospital primarily for the care and treatment of mentally ill or tuberculous patients) or is operated in connection with a hospital, or

(2) in which such nursing care and medical services are prescribed by, or are performed under the general direction of, persons licensed to practice medicine or surgery in the State.

(i) The term "construction" includes construction of new buildings, expansion, remodeling, and alteration of existing buildings, and initial equipment of any such buildings (including medical transportation facilities) and, in any case in which it will help to provide a service not previously provided in the community, equipment of any buildings; including architects' fees, but excluding the cost of off-site improvements and, except with respect to public health centers, the cost of the acquisition of land.

(j) The term "cost" as applied to construction or modernization means the amount found by the Surgeon General to be necessary

for construction and modernization respectively, under a project, except that such term, as applied to a project for modernization of a facility for which a grant or loan is to be made from an allotment under section 602(a)(2), does not include any amount found by the Surgeon General to be attributable to expansion of the bed capacity of such facility.

(k) The term "modernization" includes alteration, major repair (to the extent permitted by regulations), remodeling, replacement, and renovation of existing buildings (including initial equipment thereof), and replacement of obsolete, built-in (as determined in accordance with regulations) equipment of existing buildings.

(l) The term "title," when used with reference to a site for a project, means a fee simple, or such other estate or interest (including a leasehold on which the rental does not exceed 4 per centum of the value of the land) as the Surgeon General finds sufficient to assure for a period of not less than fifty years' undisturbed use and possession for the purposes of construction and operation of the project.

FINANCIAL STATEMENTS

SEC. 646. [2910-1] In the case of any facility for which a grant, loan, or loan guarantee has been made under this title, the applicant for such grant, loan, or loan guarantee (or, if appropriate, such other person as the Secretary may prescribe) shall file at least annually with the State agency for the State in which the facility is located a statement which shall be in such form, and contain such information, as the Secretary may require to accurately show—

(1) the financial operations of the facility, and

(2) the costs to the facility of providing health services in the facility and the charges made by the facility for providing such services,

during the period with respect to which the statement is filed.

TITLE VII—HEALTH PROFESSIONS EDUCATION

PART A—STUDENT LOANS

Subpart I—Insured Health Education Assistance Loans to Graduate Students

SEC. 701. [292] STATEMENT OF PURPOSE.

The purpose of this subpart is to enable the Secretary to provide a Federal program of student loan insurance for students in (and certain former students of) eligible institutions (as defined in section 719).

SEC. 702. [292a] SCOPE AND DURATION OF LOAN INSURANCE PROGRAM.

(a) IN GENERAL.—The total principal amount of new loans made and installments paid pursuant to lines of credit (as defined in section 719) to borrowers covered by Federal loan insurance under this subpart shall not exceed \$350,000,000 for fiscal year 1993, \$375,000,000 for fiscal year 1994, and \$425,000,000 for fiscal year 1995. If the total amount of new loans made and installments paid pursuant to lines of credit in any fiscal year is less than the ceiling established for such year, the difference between the loans made and installments paid and the ceiling shall be carried over to the next fiscal year and added to the ceiling applicable to that fiscal year, and if in any fiscal year no ceiling has been established, any difference carried over shall constitute the ceiling for making new loans (including loans to new borrowers) and paying installments for such fiscal year. Thereafter, Federal loan insurance pursuant to this subpart may be granted only for loans made (or for loan installments paid pursuant to lines of credit) to enable students, who have obtained prior loans insured under this subpart, to continue or complete their educational program or to obtain a loan under section 705(a)(1)(B) to pay interest on such prior loans; but no insurance may be granted for any loan made or installment paid after September 30, 1998. The total principal amount of Federal loan insurance available under this subsection shall be granted by the Secretary without regard to any apportionment for the purpose of chapter 15 of title 31, United States Code, and without regard to any similar limitation.

(b) CERTAIN LIMITATIONS AND PRIORITIES.—

(1) LIMITATIONS REGARDING LENDERS, STATES, OR AREAS.—The Secretary may, if necessary to assure an equitable distribution of the benefits of this subpart, assign, within the maximum amounts specified in subsection (a), Federal loan insurance quotas applicable to eligible lenders, or to States or areas, and may from time to time reassign unused portions of these quotas.

(2) PRIORITY FOR CERTAIN LENDERS.—In providing certificates of insurance under section 706 through comprehensive contracts, the Secretary shall give priority to eligible lenders that agree—

(A) to make loans to students at interest rates below the rates prevailing, during the period involved, for loans covered by Federal loan insurance pursuant to this subpart; or

(B) to make such loans under terms that are otherwise favorable to the student relative to the terms under which eligible lenders are generally making such loans during such period.

(c) AUTHORITY OF STUDENT LOAN MARKETING ASSOCIATION.—

(1) IN GENERAL.—Subject to paragraph (2), the Student Loan Marketing Association, established under part B of title IV of the Higher Education Act of 1965, is authorized to make advances on the security of, purchase, service, sell, consolidate, or otherwise deal in loans which are insured by the Secretary under this subpart, except that if any loan made under this subpart is included in a consolidated loan pursuant to the authority of the Association under part B of title IV of the Higher Education Act of 1965, the interest rate on such consolidated loan shall be set at the weighted average interest rate of all such loans offered for consolidation and the resultant per centum shall be rounded downward to the nearest one-eighth of 1 per centum, except that the interest rate shall be no less than the applicable interest rate of the guaranteed student loan program established under part B of title IV of the Higher Education Act of 1965. In the case of such a consolidated loan, the borrower shall be responsible for any interest which accrues prior to the beginning of the repayment period of the loan, or which accrues during a period in which principal need not be paid (whether or not such principal is in fact paid) by reason of any provision of the Higher Education Act of 1965.

(2) APPLICABILITY OF CERTAIN FEDERAL REGULATIONS.—With respect to Federal regulations for lenders, this subpart may not be construed to preclude the applicability of such regulations to the Student Loan Marketing Association or to any other entity in the business of purchasing student loans, including such regulations with respect to applications, contracts, and due diligence.

SEC. 703. [292b] LIMITATIONS ON INDIVIDUAL INSURED LOANS AND ON LOAN INSURANCE.

(a) IN GENERAL.—The total of the loans made to a student in any academic year or its equivalent (as determined by the Secretary) which may be covered by Federal loan insurance under this

subpart may not exceed \$20,000 in the case of a student enrolled in a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, or podiatric medicine, and \$12,500 in the case of a student enrolled in a school of pharmacy, public health, allied health, or chiropractic, or a graduate program in health administration or clinical psychology. The aggregate insured unpaid principal amount for all such insured loans made to any borrower shall not at any time exceed \$80,000 in the case of a borrower who is or was a student enrolled in a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, or podiatric medicine, and \$50,000 in the case of a borrower who is or was a student enrolled in a school of pharmacy, public health, allied health, or chiropractic, or a graduate program in health administration or clinical psychology. The annual insurable limit per student shall not be exceeded by a line of credit under which actual payments by the lender to the borrower will not be made in any year in excess of the annual limit.

(b) **EXTENT OF INSURANCE LIABILITY.**—The insurance liability on any loan insured by the Secretary under this subpart shall be 100 percent of the unpaid balance of the principal amount of the loan plus interest. The full faith and credit of the United States is pledged to the payment of all amounts which may be required to be paid under the provisions of section 707 or 714.

SEC. 704. [292c] SOURCES OF FUNDS.

Loans made by eligible lenders in accordance with this subpart shall be insurable by the Secretary whether made from funds fully owned by the lender or from funds held by the lender in a trust or similar capacity and available for such loans.

SEC. 705. [292d] ELIGIBILITY OF BORROWERS AND TERMS OF INSURED LOANS.

(a) **IN GENERAL.**—A loan by an eligible lender shall be insurable by the Secretary under the provisions of this subpart only if—

(1) made to—

(A) a student who—

(i)(I) has been accepted for enrollment at an eligible institution, or (II) in the case of a student attending an eligible institution, is in good standing at that institution, as determined by the institution;

(ii) is or will be a full-time student at the eligible institution;

(iii) has agreed that all funds received under such loan shall be used solely for tuition, other reasonable educational expenses, including fees, books, and laboratory expenses, and reasonable living expenses, incurred by such students;

(iv) if required under section 3 of the Military Selective Service Act to present himself for and submit to registration under such section, has presented himself and submitted to registration under such section; and

(v) in the case of a pharmacy student, has satisfactorily completed three years of training; or

(B) an individual who—

(i) has previously had a loan insured under this subpart when the individual was a full-time student at an eligible institution;

(ii) is in a period during which, pursuant to paragraph (2), the principal amount of such previous loan need not be paid;

(iii) has agreed that all funds received under the proposed loan shall be used solely for repayment of interest due on previous loans made under this subpart; and

(iv) if required under section 3 of the Military Selective Service Act to present himself for and submit to registration under such section, has presented himself and submitted to registration under such section;

(2) evidenced by a note or other written agreement which—

(A) is made without security and without endorsement, except that if the borrower is a minor and such note or other written agreement executed by him would not, under the applicable law, create a binding obligation, an endorsement may be required;

(B) provides for repayment of the principal amount of the loan in installments over a period of not less than 10 years (unless sooner repaid) nor more than 25 years beginning not earlier than 9 months nor later than 12 months after the date of—

(i) the date on which—

(I) the borrower ceases to be a participant in an accredited internship or residency program of not more than four years in duration;

(II) the borrower completes the fourth year of an accredited internship or residency program of more than four years in duration; or

(III) the borrower, if not a participant in a program described in subclause (I) or (II), ceases to carry, at an eligible institution, the normal full-time academic workload as determined by the institution; or

(ii) the date on which a borrower who is a graduate of an eligible institution ceases to be a participant in a fellowship training program not in excess of two years or a participant in a full-time educational activity not in excess of two years, which—

(I) is directly related to the health profession for which the borrower prepared at an eligible institution, as determined by the Secretary; and

(II) may be engaged in by the borrower during such a two-year period which begins within twelve months after the completion of the borrower's participation in a program described in subclause (I) or (II) of clause (i) or prior to the completion of the borrower's participation in such program,

except as provided in subparagraph (C), except that the period of the loan may not exceed 33 years from the date

of execution of the note or written agreement evidencing it, and except that the note or other written instrument may contain such provisions relating to repayment in the event of default in the payment of interest or in the payment of the costs of insurance premiums, or other default by the borrower, as may be authorized by regulations of the Secretary in effect at the time the loan is made;

(C) provides that periodic installments of principal and interest need not be paid, but interest shall accrue, during any period (i) during which the borrower is pursuing a full-time course of study at an eligible institution (or at an institution defined by section 481(a) of the Higher Education Act of 1965); (ii) not in excess of four years during which the borrower is a participant in an accredited internship or residency program (including any period in such a program described in subclause (I) or subclause (II) of subparagraph (B)(i)); (iii) not in excess of three years, during which the borrower is a member of the Armed Forces of the United States; (iv) not in excess of three years during which the borrower is in service as a volunteer under the Peace Corps Act; (v) not in excess of three years during which the borrower is a member of the National Health Service Corps; (vi) not in excess of three years during which the borrower is in service as a full-time volunteer under title I of the Domestic Volunteer Service Act of 1973; (vii) not in excess of 3 years, for a borrower who has completed an accredited internship or residency training program in osteopathic general practice, family medicine, general internal medicine, preventive medicine, or general pediatrics and who is practicing primary care; (viii) not in excess of 1 year, for borrowers who are graduates of schools of chiropractic; (ix) any period not in excess of two years which is described in subparagraph (B)(ii); and (x) in addition to all other deferments for which the borrower is eligible under clauses (i) through (ix), any period during which the borrower is a member of the Armed Forces on active duty during the Persian Gulf conflict, and any period described in clauses (i) through (x) shall not be included in determining the 25-year period described in subparagraph (B);

(D) provides for interest on the unpaid principal balance of the loan at a yearly rate, not exceeding the applicable maximum rate prescribed and defined by the Secretary (within the limits set forth in subsection (b)) on a national, regional, or other appropriate basis, which interest shall be compounded not more frequently than annually and payable in installments over the period of the loan except as provided in subparagraph (C), except that the note or other written agreement may provide that payment of any interest may be deferred until not later than the date upon which repayment of the first installment of principal falls due or the date repayment of principal is required to resume (whichever is applicable) and may further provide that, on such date, the amount of the interest which has

so accrued may be added to the principal for the purposes of calculating a repayment schedule;

(E) offers, in accordance with criteria prescribed by regulation by the Secretary, a schedule for repayment of principal and interest under which payment of a portion of the principal and interest otherwise payable at the beginning of the repayment period (as defined in such regulations) is deferred until a later time in the period;

(F) entitles the borrower to accelerate without penalty repayment of the whole or any part of the loan;

(G) provides that the check for the proceeds of the loan shall be made payable jointly to the borrower and the eligible institution in which the borrower is enrolled; and

(H) contains such other terms and conditions consistent with the provisions of this subpart and with the regulations issued by the Secretary pursuant to this subpart, as may be agreed upon by the parties to such loan, including, if agreed upon, a provision requiring the borrower to pay to the lender, in addition to principal and interest, amounts equal to the insurance premiums payable by the lender to the Secretary with respect to such loan; and

(3) subject to the consent of the student and subject to applicable law, the eligible lender has obtained from the student appropriate demographic information regarding the student, including racial or ethnic background.

(b) **LIMITATION ON RATE OF INTEREST.**—The rate of interest prescribed and defined by the Secretary for the purpose of subsection (a)(2)(D) may not exceed the average of the bond equivalent rates of the 91-day Treasury bills auctioned for the previous quarter plus 3 percentage points, rounded to the next higher one-eighth of 1 percent.

(c) **MINIMUM ANNUAL PAYMENT BY BORROWER.**—The total of the payments by a borrower during any year or any repayment period with respect to the aggregate amount of all loans to that borrower which are insured under this subpart shall not be less than the annual interest on the outstanding principal, except as provided in subsection (a)(2)(C), unless the borrower, in the written agreement described in subsection (a)(2), agrees to make payments during any year or any repayment period in a lesser amount.

(d) **APPLICABILITY OF CERTAIN LAWS ON RATE OR AMOUNT OF INTEREST.**—No provision of any law of the United States (other than subsections (a)(2)(D) and (b)) or of any State that limits the rate or amount of interest payable on loans shall apply to a loan insured under this subpart.

(e) **DETERMINATION REGARDING FORBEARANCE.**—Any period of time granted to a borrower under this subpart in the form of forbearance on the loan shall not be included in the 25-year total loan repayment period under subsection (a)(2)(C).

(f) **LOAN REPAYMENT SCHEDULE.**—Lenders and holders under this subpart shall offer borrowers graduated loan repayment schedules that, during the first 5 years of loan repayment, are based on the borrower's debt-to-income ratio.

(g) **RULE OF CONSTRUCTION REGARDING DETERMINATION OF NEED OF STUDENTS.**—With respect to any determination of the fi-

nancial need of a student for a loan covered by Federal loan insurance under this subpart, this subpart may not be construed to limit the authority of any school to make such allowances for students with special circumstances as the school determines appropriate.

(h) DEFINITIONS.—For purposes of this section:

(1) The term “active duty” has the meaning given such term in section 101(18) of title 37, United States Code, except that such term does not include active duty for training.

(2) The term “Persian Gulf conflict” means the period beginning on August 2, 1990, and ending on the date thereafter prescribed by Presidential proclamation or by law.

SEC. 706. [292e] CERTIFICATE OF LOAN INSURANCE; EFFECTIVE DATE OF INSURANCE.

(a) IN GENERAL.—

(1) AUTHORITY FOR ISSUANCE OF CERTIFICATE.—If, upon application by an eligible lender, made upon such form, containing such information, and supported by such evidence as the Secretary may require, and otherwise in conformity with this section, the Secretary finds that the applicant has made a loan to an eligible borrower which is insurable under the provisions of this subpart, he may issue to the applicant a certificate of insurance covering the loan and setting forth the amount and terms of the insurance.

(2) EFFECTIVE DATE OF INSURANCE.—Insurance evidenced by a certificate of insurance pursuant to subsection (a)(1) shall become effective upon the date of issuance of the certificate, except that the Secretary is authorized, in accordance with regulations, to issue commitments with respect to proposed loans, or with respect to lines (or proposed lines) of credit, submitted by eligible lenders, and in that event, upon compliance with subsection (a)(1) by the lender, the certificate of insurance may be issued effective as of the date when any loan, or any payment by the lender pursuant to a line of credit, to be covered by such insurance is made to a student described in section 705(a)(1). Such insurance shall cease to be effective upon 60 days' default by the lender in the payment of any installment of the premiums payable pursuant to section 708.

(3) CERTAIN AGREEMENTS FOR LENDERS.—An application submitted pursuant to subsection (a)(1) shall contain—

(A) an agreement by the applicant to pay, in accordance with regulations, the premiums fixed by the Secretary pursuant to section 708; and

(B) an agreement by the applicant that if the loan is covered by insurance the applicant will submit such supplementary reports and statements during the effective period of the loan agreement, upon such forms, at such times, and containing such information as the Secretary may prescribe by or pursuant to regulation.

(b) AUTHORITY REGARDING COMPREHENSIVE INSURANCE COVERAGE.—

(1) IN GENERAL.—In lieu of requiring a separate insurance application and issuing a separate certificate of insurance for each loan made by an eligible lender as provided in subsection (a), the Secretary may, in accordance with regulations consist-

ent with section 702, issue to any eligible lender applying therefor a certificate of comprehensive insurance coverage which shall, without further action by the Secretary, insure all insurable loans made by that lender, on or after the date of the certificate and before a specified cutoff date, within the limits of an aggregate maximum amount stated in the certificate. Such regulations may provide for conditioning such insurance, with respect to any loan, upon compliance by the lender with such requirements (to be stated or incorporated by reference in the certificate) as in the Secretary's judgment will best achieve the purpose of this subsection while protecting the financial interest of the United States and promoting the objectives of this subpart, including (but not limited to) provisions as to the reporting of such loans and information relevant thereto to the Secretary and as to the payment of initial and other premiums and the effect of default therein, and including provision for confirmation by the Secretary from time to time (through endorsement of the certificate) of the coverage of specific new loans by such certificate, which confirmation shall be incontestable by the Secretary in the absence of fraud or misrepresentation of fact or patent error.

(2) **LINES OF CREDIT BEYOND CUTOFF DATE.**—If the holder of a certificate of comprehensive insurance coverage issued under this subsection grants to a borrower a line of credit extending beyond the cutoff date specified in that certificate, loans or payments thereon made by the holder after that date pursuant to the line of credit shall not be deemed to be included in the coverage of that certificate except as may be specifically provided therein; but, subject to the limitations of section 702, the Secretary may, in accordance with regulations, make commitments to insure such future loans or payments, and such commitments may be honored either as provided in subsection (a) or by inclusion of such insurance in comprehensive coverage under this subsection for the period or periods in which such future loans or payments are made.

(c) **ASSIGNMENT OF INSURANCE RIGHTS.**—The rights of an eligible lender arising under insurance evidenced by a certificate of insurance issued to it under this section may be assigned by such lender, subject to regulation by the Secretary, only to—

(1) another eligible lender (including a public entity in the business of purchasing student loans); or

(2) the Student Loan Marketing Association.

(d) **EFFECT OF CONSOLIDATION OF OBLIGATIONS.**—The consolidation of the obligations of two or more federally insured loans obtained by a borrower in any fiscal year into a single obligation evidenced by a single instrument of indebtedness shall not affect the insurance by the United States. If the loans thus consolidated are covered by separate certificates of insurance issued under subsection (a), the Secretary may upon surrender of the original certificates issue a new certificate of insurance in accordance with that subsection upon the consolidated obligation. If the loans thus consolidated are covered by a single comprehensive certificate issued under subsection (b), the Secretary may amend that certificate accordingly.

(e) **RULE OF CONSTRUCTION REGARDING CONSOLIDATION OF DEBTS.**—Nothing in this section shall be construed to preclude the lender and the borrower, by mutual agreement, from consolidating all of the borrower's debts into a single instrument under the terms applicable to an insured loan made at the same time as the consolidation. The lender or loan holder should provide full information to the borrower concerning the advantages and disadvantages of loan consolidation. Nothing in this section shall be construed to preclude the consolidation of the borrower's loans insured under this subpart under section 428C of the Higher Education Act of 1965. Any loans insured pursuant to this subpart that are consolidated under section 428C of such Act shall not be eligible for special allowance payments under section 438 of such Act.

SEC. 707. [292f] DEFAULT OF BORROWER.

(a) **CONDITIONS FOR PAYMENT TO BENEFICIARY.**—Upon default by the borrower on any loan covered by Federal loan insurance pursuant to this subpart, and after a substantial collection effort (including, subject to subsection (h), commencement and prosecution of an action) as determined under regulations of the Secretary, the insurance beneficiary shall promptly notify the Secretary and the Secretary shall, if requested (at that time or after further collection efforts) by the beneficiary, or may on his own motion, if the insurance is still in effect, pay to the beneficiary the amount of the loss sustained by the insured upon that loan as soon as that amount has been determined. Not later than one year after the date of the enactment of the Health Professions Education Extension Amendments of 1992, the Secretary shall establish performance standards for lenders and holders of loans under this subpart, including fees to be imposed for failing to meet such standards.

(b) **SUBROGATION.**—Upon payment by the Secretary of the amount of the loss pursuant to subsection (a), the United States shall be subrogated for all of the rights of the holder of the obligation upon the insured loan and shall be entitled to an assignment of the note or other evidence of the insured loan by the insurance beneficiary. If the net recovery made by the Secretary on a loan after deduction of the cost of that recovery (including reasonable administrative costs) exceeds the amount of the loss, the excess shall be paid over to the insured. The Secretary may sell without recourse to eligible lenders (or other entities that the Secretary determines are capable of dealing in such loans) notes or other evidence of loans received through assignment under the first sentence.

(c) **FORBEARANCE.**—Nothing in this section or in this subpart shall be construed to preclude any forbearance for the benefit of the borrower which may be agreed upon by the parties to the insured loan and approved by the Secretary or to preclude forbearance by the Secretary in the enforcement of the insured obligation after payment on that insurance.

(d) **REASONABLE CARE AND DILIGENCE REGARDING LOANS.**—Nothing in this section or in this subpart shall be construed to excuse the eligible lender or holder of a federally insured loan from exercising reasonable care and diligence in the making of loans under the provisions of this subpart and from exercising a substan-

tial effort in the collection of loans under the provisions of this subpart. If the Secretary, after reasonable notice and opportunity for hearing to an eligible lender, finds that the lender has failed to exercise such care and diligence, to exercise such substantial efforts, to make the reports and statements required under section 706(a)(3), or to pay the required Federal loan insurance premiums, he shall disqualify that lender from obtaining further Federal insurance on loans granted pursuant to this subpart until he is satisfied that its failure has ceased and finds that there is reasonable assurance that the lender will in the future exercise necessary care and diligence, exercise substantial effort, or comply with such requirements, as the case may be.

(e) DEFINITIONS.—For purposes of this section:

(1) The term "insurance beneficiary" means the insured or its authorized assignee in accordance with section 706(c).

(2) The term "amount of the loss" means, with respect to a loan, unpaid balance of the principal amount and interest on such loan, less the amount of any judgment collected pursuant to default proceedings commenced by the eligible lender or holder involved.

(3) The term "default" includes only such defaults as have existed for 120 days.

(f) REDUCTIONS IN FEDERAL REIMBURSEMENTS OR PAYMENTS FOR DEFAULTING BORROWERS.—The Secretary shall, after notice and opportunity for a hearing, cause to be reduced Federal reimbursements or payments for health services under any Federal law to borrowers who are practicing their professions and have defaulted on their loans insured under this subpart in amounts up to the remaining balance of such loans. Procedures for reduction of payments under the medicare program are provided under section 1892 of the Social Security Act. Notwithstanding such section 1892, any funds recovered under this subsection shall be deposited in the insurance fund established under section 710.

(g) CONDITIONS FOR DISCHARGE OF DEBT IN BANKRUPTCY.—A debt which is a loan insured under the authority of this subpart may be released by a discharge in bankruptcy under any chapter of title 11, United States Code, only if such discharge is granted—

(1) after the expiration of the seven-year period beginning on the first date when repayment of such loan is required, exclusive of any period after such date in which the obligation to pay installments on the loan is suspended;

(2) upon a finding by the Bankruptcy Court that the nondischarge of such debt would be unconscionable; and

(3) upon the condition that the Secretary shall not have waived the Secretary's rights to apply subsection (f) to the borrower and the discharged debt.

(h) REQUIREMENT REGARDING ACTIONS FOR DEFAULT.—

(1) IN GENERAL.—With respect to the default by a borrower on any loan covered by Federal loan insurance under this subpart, the Secretary shall, under subsection (a), require an eligible lender or holder to commence and prosecute an action for such default unless—

(A) in the determination of the Secretary—

(i) the eligible lender or holder has made reasonable efforts to serve process on the borrower involved and has been unsuccessful with respect to such efforts, or

(ii) prosecution of such an action would be fruitless because of the financial or other circumstances of the borrower;

(B) for such loans made before the date of the enactment of the Health Professions Reauthorization Act of 1988, the loan involved was made in an amount of less than \$5,000; or

(C) for such loans made after such date, the loan involved was made in an amount of less than \$2,500.

(2) RELATIONSHIP TO CLAIM FOR PAYMENT.—With respect to an eligible lender or holder that has commenced an action pursuant to subsection (a), the Secretary shall make the payment required in such subsection, or deny the claim for such payment, not later than 60 days after the date on which the Secretary determines that the lender or holder has made reasonable efforts to secure a judgment and collect on the judgment entered into pursuant to this subsection.

(3) STATE COURT JUDGMENTS.—With respect to any State court judgment that is obtained by a lender or holder against a borrower for default on a loan insured under this subpart and that is subrogated to the United States under subsection (b), any United States attorney may register such judgment with the Federal courts for enforcement.

(i) INAPPLICABILITY OF FEDERAL AND STATE STATUTE OF LIMITATIONS ON ACTIONS FOR LOAN COLLECTION.—Notwithstanding any other provision of Federal or State law, there shall be no limitation on the period within which suit may be filed, a judgment may be enforced, or an offset, garnishment, or other action may be initiated or taken by the Secretary, the Attorney General, or other administrative head of another Federal agency, as the case may be, for the repayment of the amount due from a borrower on a loan made under this subpart that has been assigned to the Secretary under subsection (b).

(j) SCHOOL COLLECTION ASSISTANCE.—An institution or postgraduate training program attended by a borrower may assist in the collection of any loan of that borrower made under this subpart which becomes delinquent, including providing information concerning the borrower to the Secretary and to past and present lenders and holders of the borrower's loans, contacting the borrower in order to encourage repayment, and withholding services in accordance with regulations issued by the Secretary under section 715(a)(7). The institution or postgraduate training program shall not be subject to section 809 of the Fair Debt Collection Practices Act for purposes of carrying out activities authorized by this section.

SEC. 708. [292g] RISK-BASED PREMIUMS.

(a) AUTHORITY.—With respect to a loan made under this subpart on or after January 1, 1993, the Secretary, in accordance with subsection (b), shall assess a risk-based premium on an eligible

borrower and, if required under this section, an eligible institution that is based on the default rate of the eligible institution involved (as defined in section 719).

(b) **ASSESSMENT OF PREMIUM.**—Except as provided in subsection (d)(2), the risk-based premium to be assessed under subsection (a) shall be as follows:

(1) **LOW-RISK RATE.**—With respect to an eligible borrower seeking to obtain a loan for attendance at an eligible institution that has a default rate of not to exceed five percent, such borrower shall be assessed a risk-based premium in an amount equal to 6 percent of the principal amount of the loan.

(2) **MEDIUM-RISK RATE.**—

(A) **IN GENERAL.**—With respect to an eligible borrower seeking to obtain a loan for attendance at an eligible institution that has a default rate of in excess of five percent but not to exceed 10 percent—

(i) such borrower shall be assessed a risk-based premium in an amount equal to 8 percent of the principal amount of the loan; and

(ii) such institution shall be assessed a risk-based premium in an amount equal to 5 percent of the principal amount of the loan.

(B) **DEFAULT MANAGEMENT PLAN.**—An institution of the type described in subparagraph (A) shall prepare and submit to the Secretary for approval, an annual default management plan, that shall specify the detailed short-term and long-term procedures that such institution will have in place to minimize defaults on loans to borrowers under this subpart. Under such plan the institution shall, among other measures, provide an exit interview to all borrowers that includes information concerning repayment schedules, loan deferments, forbearance, and the consequences of default.

(3) **HIGH-RISK RATE.**—

(A) **IN GENERAL.**—With respect to an eligible borrower seeking to obtain a loan for attendance at an eligible institution that has a default rate of in excess of 10 percent but not to exceed 20 percent—

(i) such borrower shall be assessed a risk-based premium in an amount equal to 8 percent of the principal amount of the loan; and

(ii) such institution shall be assessed a risk-based premium in an amount equal to 10 percent of the principal amount of the loan.

(B) **DEFAULT MANAGEMENT PLAN.**—An institution of the type described in subparagraph (A) shall prepare and submit to the Secretary for approval a plan that meets the requirements of paragraph (2)(B).

(4) **INELIGIBILITY.**—An individual shall not be eligible to obtain a loan under this subpart for attendance at an institution that has a default rate in excess of 20 percent.

(c) **REDUCTION OF RISK-BASED PREMIUM.**—Lenders shall reduce by 50 percent the risk-based premium to eligible borrowers if a

credit worthy parent or other responsible party co-signs the loan note.

(d) **ADMINISTRATIVE WAIVERS.**—

(1) **HEARING.**—The Secretary shall afford an institution not less than one hearing, and may consider mitigating circumstances, prior to making such institution ineligible for participation in the program under this subpart.

(2) **EXCEPTIONS.**—In carrying out this section with respect to an institution, the Secretary may grant an institution a waiver of requirements of paragraphs (2) through (4) of subsection (b) if the Secretary determines that the default rate for such institution is not an accurate indicator because the volume of the loans under this subpart made by such institution has been insufficient.

(3) **TRANSITION FOR CERTAIN INSTITUTIONS.**—During the 3-year period beginning on the effective date of the Health Professions Education Extension Amendments of 1992—

(A) subsection (b)(4) shall not apply with respect to any eligible institution that is a Historically Black College or University; and

(B) any such institution that has a default rate in excess of 20 percent, and any eligible borrower seeking a loan for attendance at the institution, shall be subject to subsection (b)(3) to the same extent and in the same manner as eligible institutions and borrowers described in such subsection.

(e) **PAYOFF TO REDUCE RISK CATEGORY.**—An institution may pay off the outstanding principal and interest owed by the borrowers of such institution who have defaulted on loans made under this subpart in order to reduce the risk category of the institution.

SEC. 709. [292h] OFFICE FOR HEALTH EDUCATION ASSISTANCE LOAN DEFAULT REDUCTION.

(a) **ESTABLISHMENT.**—The Secretary shall establish, within the Division of Student Assistance of the Bureau of Health Professions, an office to be known as the Office for Health Education Assistance Loan Default Reduction (in this section referred to as the "Office").

(b) **PURPOSE AND FUNCTIONS.**—It shall be the purpose of the Office to achieve a reduction in the number and amounts of defaults on loans guaranteed under this subpart. In carrying out such purpose the Office shall—

(1) conduct analytical and evaluative studies concerning loans and loan defaults;

(2) carry out activities designed to reduce loan defaults;

(3) respond to special circumstances that may exist in the financial lending environment that may lead to loan defaults;

(4) coordinate with other Federal entities that are involved with student loan programs, including—

(A) with respect to the Department of Education, in the development of a single student loan application form, a single student loan deferment form, a single disability form, and a central student loan database; and

(B) with respect to the Department of Justice, in the recovery of payments from health professionals who have defaulted on loans guaranteed under this subpart;

(5) provide technical assistance to borrowers, lenders, holders, and institutions concerning deferments and collection activities; and

(6) prepare and submit a report not later than March 31, 1993, and annually, thereafter, to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives concerning—

(A) the default rates for each—

(i) institution described in section 719(1) that is participating in the loan programs under this subpart;

(ii) lender participating in the loan program under this subpart; and

(iii) loan holder under this subpart;

(B) the total amounts recovered pursuant to section 707(b) during the preceding fiscal year; and

(C) a plan for improving the extent of such recoveries during the current fiscal year.

(c) ADDITIONAL DUTIES.—In conjunction with the report submitted under subsection (b), the Office shall—

(1) compile, and publish in the Federal Register, a list of the borrowers who are in default under this subpart; and

(2) send the report and notices of default with respect to these borrowers to relevant Federal agencies and to schools, school associations, professional and specialty associations, State licensing boards, hospitals with which such borrowers may be associated, and any other relevant organizations.

(d) ALLOCATION OF FUNDS FOR OFFICE.—In the case of amounts reserved under section 710(a)(2)(B) for obligation under this subsection, the Secretary may obligate the amounts for the purpose of administering the Office, including 7 full-time equivalent employment positions for such Office. With respect to such purpose, amounts made available under the preceding sentence are in addition to amounts made available to the Health Resources and Services Administration for program management for the fiscal year involved. With respect to such employment positions, the positions are in addition to the number of full-time equivalent employment positions that otherwise is authorized for the Department of Health and Human Services for the fiscal year involved.

SEC. 710. [292i] INSURANCE ACCOUNT.

(a) IN GENERAL.—

(1) ESTABLISHMENT.—There is hereby established a student loan insurance account (in this section referred to as the “Account”) which shall be available without fiscal year limitation to the Secretary for making payments in connection with the collection and default of loans insured under this subpart by the Secretary.

(2) FUNDING.—

(A) Except as provided in subparagraph (B), all amounts received by the Secretary as premium charges for insurance and as receipts, earnings, or proceeds derived from any claim or other assets acquired by the Secretary in connection with his operations under this subpart, and

any other moneys, property, or assets derived by the Secretary from the operations of the Secretary in connection with this section, shall be deposited in the Account.

(B) With respect to amounts described in subparagraph (A) that are received by the Secretary for any of the fiscal years 1993 through 1996, the Secretary may, before depositing such amounts in the Account, reserve from the amounts each such fiscal year not more than \$1,000,000 for obligation under section 709(d).

(3) EXPENDITURES.—All payments in connection with the default of loans insured by the Secretary under this subpart shall be paid from the Account.

(b) CONTINGENT AUTHORITY FOR ISSUANCE OF NOTES OR OTHER OBLIGATIONS.—If at any time the moneys in the Account are insufficient to make payments in connection with the collection or default of any loan insured by the Secretary under this subpart, the Secretary of the Treasury may lend the Account such amounts as may be necessary to make the payments involved, subject to the Federal Credit Reform Act of 1990.

SEC. 711. [292j] POWERS AND RESPONSIBILITIES OF SECRETARY.

(a) IN GENERAL.—In the performance of, and with respect to, the functions, powers, and duties vested in the Secretary by this subpart, the Secretary is authorized as follows:

(1) To prescribe such regulations as may be necessary to carry out the purposes of this subpart.

(2) To sue and be sued in any district court of the United States. Such district courts shall have jurisdiction of civil actions arising under this subpart without regard to the amount in controversy, and any action instituted under this subsection by or against the Secretary shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in that office. No attachment, injunction, garnishment, or other similar process, mesne or final, shall be issued against the Secretary or property under the control of the Secretary. Nothing herein shall be constructed to except litigation arising out of activities under this subpart from the application of sections 517 and 547 of title 28 of the United States Code.

(3) To include in any contract for Federal loan insurance such terms, conditions, and covenants relating to repayment of principal and payments of interest, relating to his obligations and rights and to those of eligible lenders, and borrowers in case of default, and relating to such other matters as the Secretary determines to be necessary to assure that the purposes of this subpart will be achieved. Any term, condition, and covenant made pursuant to this paragraph or any other provisions of this subpart may be modified by the Secretary if the Secretary determines that modification is necessary to protect the financial interest of the United States.

(4) Subject to the specific limitations in the subpart, to consent to the modification of any note or other instrument evidencing a loan which has been insured by him under this subpart (including modifications with respect to the rate of inter-

est, time of payment of any installment of principal and interest or any portion thereof, or any other provision).

(5) To enforce, pay, compromise, waive, or release any right, title, claim, lien, or demand, however acquired, including any equity or any right or redemption.

(b) **ANNUAL BUDGET; ACCOUNTS.**—The Secretary shall, with respect to the financial operations arising by reason of this subpart—

(1) prepare annually and submit a budget program as provided for wholly owned Government corporations by the Government Corporation Control Act; and

(2) maintain with respect to insurance under this subpart an integral set of accounts.

SEC. 712. [292k] PARTICIPATION BY FEDERAL CREDIT UNIONS IN FEDERAL, STATE, AND PRIVATE STUDENT LOAN INSURANCE PROGRAMS.

Notwithstanding any other provision of law, Federal credit unions shall, pursuant to regulations of the Administrator of the National Credit Union Administration, have power to make insured loans to eligible students in accordance with the provisions of this subpart relating to Federal insured loans.

SEC. 713. [292l] DETERMINATION OF ELIGIBLE STUDENTS.

For purposes of determining eligible students under this part, in the case of a public school in a State that offers an accelerated, integrated program of study combining undergraduate premedical education and medical education leading to advanced entry, by contractual agreement, into an accredited four-year school of medicine which provides the remaining training leading to a degree of doctor of medicine, whenever in this part a provision refers to a student at a school of medicine, such reference shall include only a student enrolled in any of the last four years of such accelerated, integrated program of study.

SEC. 714. [292m] REPAYMENT BY SECRETARY OF LOANS OF DECEASED OR DISABLED BORROWERS.

If a borrower who has received a loan dies or becomes permanently and totally disabled (as determined in accordance with regulations of the Secretary), the Secretary shall discharge the borrower's liability on the loan by repaying the amount owed on the loan from the account established under section 710.

SEC. 715. [292n] ADDITIONAL REQUIREMENTS FOR INSTITUTIONS AND LENDERS.

(a) **IN GENERAL.**—Notwithstanding any other provision of this subpart, the Secretary is authorized to prescribe such regulations as may be necessary to provide for—

(1) a fiscal audit of an eligible institution with regard to any funds obtained from a borrower who has received a loan insured under this subpart;

(2) the establishment of reasonable standards of financial responsibility and appropriate institutional capability for the administration by an eligible institution of a program of student financial aid with respect to funds obtained from a student who has received a loan insured under this subpart;

(3) the limitation, suspension, or termination of the eligibility under this subpart of any otherwise eligible institution,

whenever the Secretary has determined, after notice and affording an opportunity for hearing, that such institution has violated or failed to carry out any regulation prescribed under this subpart;

(4) the collection of information from the borrower, lender, or eligible institution to assure compliance with the provisions of section 705;

(5) the assessing of tuition or fees to borrowers in amounts that are the same or less than the amount of tuition and fees assessed to nonborrowers;

(6) the submission, by the institution or the lender to the Office of Health Education Assistance Loan Default Reduction, of information concerning each loan made under this subpart, including the date when each such loan was originated, the date when each such loan is sold, the identity of the loan holder and information concerning a change in the borrower's status;

(7) the withholding of services, including academic transcripts, financial aid transcripts, and alumni services, by an institution from a borrower upon the default of such borrower of a loan under this subpart, except in case of a borrower who has filed for bankruptcy; and

(8) the offering, by the lender to the borrower, of a variety of repayment options, including fixed-rate, graduated repayment with negative amortization permitted, and income dependent payments for a limited period followed by level monthly payments.

(b) **RECORDING BY INSTITUTION OF INFORMATION ON STUDENTS.**—The Secretary shall require an eligible institution to record, and make available to the lender and to the Secretary upon request, the name, address, postgraduate destination, and other reasonable identifying information for each student of such institution who has a loan insured under this subpart.

(c) **WORKSHOP FOR STUDENT BORROWERS.**—Each participating eligible institution must have, at the beginning of each academic year, a workshop concerning the provisions of this subpart that all student borrowers shall be required to attend.

SEC. 719. [292o] DEFINITIONS.

For purposes of this subpart:

(1) The term "eligible institution" means, with respect to a fiscal year, a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, allied health, or chiropractic, or a graduate program in health administration or clinical psychology.

(2) The term "eligible lender" means an eligible institution that became a lender under this subpart prior to September 15, 1992, an agency or instrumentality of a State, a financial or credit institution (including an insurance company) which is subject to examination and supervision by an agency of the United States or of any State, a pension fund approved by the Secretary for this purpose, or a nonprofit private entity des-

ignated by the State, regulated by the State, and approved by the Secretary.

(3) The term "line of credit" means an arrangement or agreement between the lender and the borrower whereby a loan is paid out by the lender to the borrower in annual installments, or whereby the lender agrees to make, in addition to the initial loan, additional loans in subsequent years.

(4) The term "school of allied health" means a program in a school of allied health (as defined in section 799) which leads to a masters' degree or a doctoral degree.

(5)(A) The term "default rate", in the case of an eligible entity, means the percentage constituted by the ratio of—

(i) the principal amount of loans insured under this subpart—

(I) that are made with respect to the entity and that enter repayment status after April 7, 1987; and

(II) for which amounts have been paid under section 707(a) to insurance beneficiaries, exclusive of any loan for which amounts have been so paid as a result of the death or total and permanent disability of the borrower; exclusive of any loan for which the borrower begins payments to the Secretary on the loan pursuant to section 707(b) and maintains payments for 12 consecutive months in accordance with the agreement involved (with the loan subsequently being included or excluded, as the case may be, as amounts paid under section 707(a) according to whether further defaults occur and whether with respect to the default involved compliance with such requirement regarding 12 consecutive months occurs); and exclusive of any loan on which payments may not be recovered by reason of the obligation under the loan being discharged in bankruptcy under title 11, United States Code; to

(ii) the total principal amount of loans insured under this subpart that are made with respect to the entity and that enter repayment status after April 7, 1987.

(B) For purposes of subparagraph (A), a loan insured under this subpart shall be considered to have entered repayment status if the applicable period described in subparagraph (B) of section 705(a)(2) regarding the loan has expired (without regard to whether any period described in subparagraph (C) of such section is applicable regarding the loan).

(C) For purposes of subparagraph (A), the term "eligible entity" means an eligible institution, an eligible lender, or a holder, as the case may be.

(D) For purposes of subparagraph (A), a loan is made with respect to an eligible entity if—

(i) in the case of an eligible institution, the loan was made to students of the institution;

(ii) in the case of an eligible lender, the loan was made by the lender; and

(iii) in the case of a holder, the loan was purchased by the holder.

SEC. 720. [292p] AUTHORIZATION OF APPROPRIATIONS.

(a) **IN GENERAL.**—For fiscal year 1993 and subsequent fiscal years, there are authorized to be appropriated such sums as may be necessary for the adequacy of the student loan insurance account under this subpart and for the purpose of administering this subpart.

(b) **AVAILABILITY OF SUMS.**—Sums appropriated under subsection (a) shall remain available until expended.

Subpart II—Federally-Supported Student Loan Funds

SEC. 721. [292q] AGREEMENTS FOR OPERATION OF SCHOOL LOAN FUNDS.

(a) **FUND AGREEMENTS.**—The Secretary is authorized to enter into an agreement for the establishment and operation of a student loan fund in accordance with this subpart with any public or other nonprofit school of medicine, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, or veterinary medicine.

(b) **REQUIREMENTS.**—Each agreement entered into under this section shall—

(1) provide for establishment of a student loan fund by the school;

(2) provide for deposit in the fund of—

(A) the Federal capital contributions to the fund;

(B) an amount equal to not less than one-ninth of such Federal capital contributions, contributed by such institution;

(C) collections of principal and interest on loans made from the fund;

(D) collections pursuant to section 722(j); and

(E) any other earnings of the fund;

(3) provide that the fund shall be used only for loans to students of the school in accordance with the agreement and for costs of collection of such loans and interest thereon;

(4) provide that loans may be made from such funds only to students pursuing a full-time course of study at the school leading to a degree of doctor of medicine, doctor of dentistry or an equivalent degree, doctor of osteopathy, bachelor of science in pharmacy or an equivalent degree, doctor of pharmacy or an equivalent degree, doctor of podiatric medicine or an equivalent degree, doctor of optometry or an equivalent degree, or doctor of veterinary medicine or an equivalent degree;

(5) provide that the school shall advise, in writing, each applicant for a loan from the student loan fund of the provisions of section 722 under which outstanding loans from the student loan fund may be paid (in whole or in part) by the Secretary; and

(6) contain such other provisions as are necessary to protect the financial interests of the United States.

(c) **FAILURE OF SCHOOL TO COLLECT LOANS.**—

(1) **IN GENERAL.**—Any standard established by the Secretary by regulation for the collection by schools of medicine, osteopathic medicine, dentistry, pharmacy, podiatric medicine,

optometry, or veterinary medicine of loans made pursuant to loan agreements under this subpart shall provide that the failure of any such school to collect such loans shall be measured in accordance with this subsection. This subsection may not be construed to require such schools to reimburse the student loan fund under this subpart for loans that became uncollectible prior to August 1985 or to penalize such schools with respect to such loans.

(2) **EXTENT OF FAILURE.**—The measurement of a school's failure to collect loans made under this subpart shall be the ratio (stated as a percentage) that the defaulted principal amount outstanding of such school bears to the matured loans of such school.

(3) **DEFINITIONS.**—For purposes of this subsection:

(A) The term "default" means the failure of a borrower of a loan made under this subpart to—

(i) make an installment payment when due; or

(ii) comply with any other term of the promissory note for such loan,

except that a loan made under this subpart shall not be considered to be in default if the loan is discharged in bankruptcy or if the school reasonably concludes from written contracts with the borrower that the borrower intends to repay the loan.

(B) The term "defaulted principal amount outstanding" means the total amount borrowed from the loan fund of a school that has reached the repayment stage (minus any principal amount repaid or canceled) on loans—

(i) repayable monthly and in default for at least 120 days; and

(ii) repayable less frequently than monthly and in default for at least 180 days;

(C) The term "grace period" means the period of one year beginning on the date on which the borrower ceases to pursue a full-time course of study at a school of medicine, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, or veterinary medicine; and

(D) The term "matured loans" means the total principal amount of all loans made by a school under this subpart minus the total principal amount of loans made by such school to students who are—

(i) enrolled in a full-time course of study at such school; or

(ii) in their grace period.

SEC. 722. [292r] LOAN PROVISIONS.

(a) **AMOUNT OF LOAN.**—

(1) **IN GENERAL.**—Loans from a student loan fund (established under an agreement with a school under section 721) may not, subject to paragraph (2), exceed for any student for a school year (or its equivalent) the sum of—

(A) the cost of tuition for such year at such school, and

(B) \$2,500.

(2) **THIRD AND FOURTH YEARS OF MEDICAL SCHOOL.**—For purposes of paragraph (1), the amount \$2,500 may, in the case of the third or fourth year of a student at school¹ of medicine or osteopathic medicine, be increased to the extent necessary (including such \$2,500) to pay the balances of loans that, from sources other than the student loan fund under section 721, were made to the individual for attendance at the school. The authority to make such an increase is subject to the school and the student agreeing that such amount (as increased) will be expended to pay such balances.

(b) **TERMS AND CONDITIONS.**—Subject to section 723, any such loans shall be made on such terms and conditions as the school may determine, but may be made only to a student—

(1) who is in need of the amount thereof to pursue a full-time course of study at the school leading to a degree of doctor of medicine, doctor of dentistry or an equivalent degree, doctor of osteopathy, bachelor of science in pharmacy or an equivalent degree, doctor of pharmacy or an equivalent degree, doctor of podiatric medicine or an equivalent degree, doctor of optometry or an equivalent degree, or doctor of veterinary medicine or an equivalent degree; and

(2) who, if required under section 3 of the Military Selective Service Act to present himself for and submit to registration under such section, has presented himself and submitted to registration under such section.

(c) **REPAYMENT; EXCLUSIONS FROM TEN-YEAR PERIOD.**—Such loans shall be repayable in equal or graduated periodic installments (with the right of the borrower to accelerate repayment) over the ten-year period which begins one year after the student ceases to pursue a full-time course of study at a school of medicine, osteopathic medicine, dentistry, pharmacy, podiatry, optometry, or veterinary medicine, excluding from such ten-year period—

(1) all periods—

(A) not in excess of three years of active duty performed by the borrower as a member of a uniformed service;

(B) not in excess of three years during which the borrower serves as a volunteer under the Peace Corps Act;

(C) during which the borrower participates in advanced professional training, including internships and residencies; and

(D) during which the borrower is pursuing a full-time course of study at such a school; and

(2) a period—

(A) not in excess of two years during which a borrower who is a full-time student in such a school leaves the school, with the intent to return to such school as a full-time student, in order to engage in a full-time educational activity which is directly related to the health profession for which the borrower is preparing, as determined by the Secretary; or

¹So in law. See section 2014(b)(1) of Public Law 103-43 (107 Stat. 215). Probably should be "student at a school".

(B) not in excess of two years during which a borrower who is a graduate of such a school is a participant in a fellowship training program or a full-time educational activity which—

(i) is directly related to the health profession for which such borrower prepared at such school, as determined by the Secretary; and

(ii) may be engaged in by the borrower during such a two-year period which begins within twelve months after the completion of the borrower's participation in advanced professional training described in paragraph (1)(C) or prior to the completion of such borrower's participation in such training.

(d) CANCELLATION OF LIABILITY.—The liability to repay the unpaid balance of such a loan and accrued interest thereon shall be canceled upon the death of the borrower, or if the Secretary determines that he has become permanently, and totally disabled.

(e) RATE OF INTEREST.—Such loans shall bear interest, on the unpaid balance of the loan, computed only for periods for which the loan is repayable, at the rate of 5 percent per year.

(f) SECURITY OR ENDORSEMENT.—Loans shall be made under this subpart without security or endorsement, except that if the borrower is a minor and the note or other evidence of obligation executed by him would not, under the applicable law, create a binding obligation, either security or endorsement may be required.

(g) TRANSFERRING AND ASSIGNING LOANS.—No note or other evidence of a loan made under this subpart may be transferred or assigned by the school making the loan except that, if the borrowers transfer to another school participating in the program under this subpart, such note or other evidence of a loan may be transferred to such other school.

(h) CHARGE WITH RESPECT TO INSURANCE FOR CERTAIN CANCELLATIONS.—Subject to regulations of the Secretary, a school may assess a charge with respect to loans made this subpart to cover the costs of insuring against cancellation of liability under subsection (d).

(i) CHARGE WITH RESPECT TO LATE PAYMENTS.—Subject to regulations of the Secretary, and in accordance with this section, a school shall assess a charge with respect to a loan made under this subpart for failure of the borrower to pay all or any part of an installment when it is due and, in the case of a borrower who is entitled to deferment of the loan under subsection (c), for any failure to file timely and satisfactory evidence of such entitlement. No such charge may be made if the payment of such installment or the filing of such evidence is made within 60 days after the date on which such installment or filing is due. The amount of any such charge may not exceed an amount equal to 6 percent of the amount of such installment. The school may elect to add the amount of any such charge to the principal amount of the loan as of the first day after the day on which such installment or evidence was due, or to make the amount of the charge payable to the school not later than the due date of the next installment after receipt by the borrower of notice of the assessment of the charge.

(j) **AUTHORITY OF SCHOOLS REGARDING RATE OF PAYMENT.**—A school may provide, in accordance with regulations of the Secretary, that during the repayment period of a loan from a loan fund established pursuant to an agreement under this subpart payments of principal and interest by the borrower with respect to all the outstanding loans made to him from loan funds so established shall be at a rate equal to not less than \$15 per month.

(k) **AUTHORITY REGARDING REPAYMENTS BY SECRETARY.**—Upon application by a person who received, and is under an obligation to repay, any loan made to such person as a health professions student to enable him to study medicine, osteopathy, dentistry, veterinary medicine, optometry, pharmacy, or podiatry, the Secretary may undertake to repay (without liability to the applicant) all or any part of such loan, and any interest or portion thereof outstanding thereon, upon his determination, pursuant to regulations establishing criteria therefor, that the applicant—

(1) failed to complete such studies leading to his first professional degree;

(2) is in exceptionally needy circumstances;

(3) is from a low-income or disadvantaged family as those terms may be defined by such regulations; and

(4) has not resumed, or cannot reasonably be expected to resume, the study of medicine, osteopathy, dentistry, veterinary medicine, optometry, pharmacy, or podiatric medicine, within two years following the date upon which he terminated such studies.

(l) **COLLECTION EFFORTS BY SECRETARY.**—The Secretary is authorized to attempt to collect any loan which was made under this subpart, which is in default, and which was referred to the Secretary by a school with which the Secretary has an agreement under this subpart, on behalf of that school under such terms and conditions as the Secretary may prescribe (including reimbursement from the school's student loan fund for expenses the Secretary may reasonably incur in attempting collection), but only if the school has complied with such requirements as the Secretary may specify by regulation with respect to the collection of loans under this subpart. A loan so referred shall be treated as a debt subject to section 5514 of title 5, United States Code. Amounts collected shall be deposited in the school's student loan fund. Whenever the Secretary desires the institution of a civil action regarding any such loan, the Secretary shall refer the matter to the Attorney General for appropriate action.

SEC. 723. [292s] MEDICAL SCHOOLS AND PRIMARY HEALTH CARE.

(a) **REQUIREMENTS FOR STUDENTS.**—

(1) **IN GENERAL.**—Subject to the provisions of this subsection, in the case of student loan funds established under section 721 by schools of medicine or osteopathic medicine, each agreement entered into under such section with such a school shall provide (in addition to the provisions required in subsection (b) of such section) that the school will make a loan from such fund to a student only if the student agrees—

(A) to enter and complete a residency training program in primary health care not later than 4 years after

the date on which the student graduates from such school; and

(B) to practice in such care through the date on which the loan is repaid in full.

(2) INAPPLICABILITY TO CERTAIN STUDENTS.—

(A) The requirement established in paragraph (1) regarding the student loan fund of a school does not apply to a student if—

(i) the first loan to the student from such fund is made before July 1, 1993; or

(ii) the loan is made from—

(I) a Federal capital contribution under section 721 that is made from amounts appropriated under section 724(f) (in this section referred to as an “exempt Federal capital contribution”); or

(II) a school contribution made under section 721 pursuant to such a Federal capital contribution (in this section referred to as an “exempt school contribution”).

(B) A Federal capital contribution under section 721 may not be construed as being an exempt Federal capital contribution if the contribution was made from amounts appropriated before October 1, 1990. A school contribution under section 721 may not be construed as being an exempt school contribution if the contribution was made pursuant to a Federal capital contribution under such section that was made from amounts appropriated before such date.

(3) NONCOMPLIANCE BY STUDENT.—Each agreement entered into with a student pursuant to paragraph (1) shall provide that, if the student fails to comply with the agreement—

(A) the balance due on the loan involved will be immediately recomputed from the date of issuance at an interest rate of 12 percent per year, compounded annually; and

(B) the recomputed balance will be paid not later than the expiration of the 3-year period beginning on the date on which the student fails to comply with the agreement.

(4) WAIVERS.—

(A) With respect to the obligation of an individual under an agreement made under paragraph (1) as a student, the Secretary shall provide for the partial or total waiver or suspension of the obligation whenever compliance by the individual is impossible, or would involve extreme hardship to the individual, and if enforcement of the obligation with respect to the individual would be unconscionable.

(B) For purposes of subparagraph (A), the obligation of an individual shall be waived if—

(i) the status of the individual as a student of the school involved is terminated before graduation from the school, whether voluntarily or involuntarily; and

(ii) the individual does not, after such termination, resume attendance at the school or begin attendance

at any other school of medicine or osteopathic medicine.

(C) If an individual resumes or begins attendance for purposes of subparagraph (B), the obligation of the individual under the agreement under paragraph (1) shall be considered to have been suspended for the period in which the individual was not in attendance.

(D) This paragraph may not be construed as authorizing the waiver or suspension of the obligation of a student to repay, in accordance with section 722, loans from student loan funds under section 721.

(b) REQUIREMENTS FOR SCHOOLS.—

(1) **IN GENERAL.**—Subject to the provisions of this subsection, in the case of student loan funds established under section 721 by schools of medicine or osteopathic medicine, each agreement entered into under such section with such a school shall provide (in addition to the provisions required in subsection (b) of such section) that, for the 1-year period ending on June 30, 1997;¹ and for the 1-year period ending on June 30 of each subsequent fiscal year, the school will meet not less than 1 of the conditions described in paragraph (2) with respect to graduates of the school whose date of graduation from the school occurred approximately 3 years before the end of the 1-year period involved.

(2) **DESCRIPTION OF CONDITIONS.**—With respect to graduates described in paragraph (1) (in this paragraph referred to as “designated graduates”), the conditions referred to in such paragraph for a school for a 1-year period are as follows:

(A) Not less than 50 percent of designated graduates of the school meet the criterion of either being in a residency training program in primary health care, or being engaged in a practice in such care (having completed such a program).

(B) Not less than 25 percent of the designated graduates of the school meet such criterion, and such percentage is not less than 5 percentage points above the percentage of such graduates meeting such criterion for the preceding 1-year period.

(C) In the case of schools of medicine or osteopathic medicine with student loans funds under section 721, the school involved is at or above the 75th percentile of such schools whose designated graduates meet such criterion.

(3) **DETERMINATIONS BY SECRETARY.**—Not later than 90 days after the close of each 1-year period described in paragraph (1), the Secretary shall make a determination of whether the school involved has for such period complied with such paragraph and shall in writing inform the school of the determination. Such determination shall be made only after consideration of the report submitted to the Secretary by the school under paragraph (6).

(4) **NONCOMPLIANCE BY SCHOOL.**—

¹ So in law. See section 2014(c)(2)(A)(i) of Public Law 103–43 (107 Stat. 216). The semicolon probably should be a comma.

(A)(i) Subject to subparagraph (C), each agreement under section 721 with a school of medicine or osteopathic medicine shall provide that, if the school fails to comply with paragraph (1) for a 1-year period under such paragraph, the school—

(I) will pay to the Secretary the amount applicable under subparagraph (B) for the period; and

(II) will pay such amount not later than 90 days after the school is informed under paragraph (3) of the determination of the Secretary regarding such period.

(ii) Any amount that a school is required to pay under clause (i) may be paid from the student loan fund of the school under section 721.

(B) For purposes of subparagraph (A), the amount applicable for a school, subject to subparagraph (C), is—

(i) for the 1-year period ending June 30, 1997, an amount equal to 10 percent of the income received during such period by the student loan fund of the school under section 721;

(ii) for the 1-year period ending June 30, 1998, an amount equal to 20 percent of the income received during such period by the student loan fund; and

(iii) for any subsequent 1-year period under paragraph (1), an amount equal to 30 percent of the income received during such period by the student loan fund.

(C) In determining the amount of income that a student loan fund has received for purposes of subparagraph (B), the Secretary shall exclude any income derived from exempt contributions. Payments made to the Secretary under subparagraph (A) may not be made with such contributions or with income derived from such contributions.

(5) EXPENDITURE OF PAYMENTS.—

(A) Amounts paid to the Secretary under paragraph (4) shall be expended to make Federal capital contributions to student loan funds under section 721 of schools that are in compliance with paragraph (1).

(B) A Federal capital contribution under section 721 may not be construed as being an exempt Federal capital contribution if the contribution is made from payments under subparagraph (A). A school contribution under such section may not be construed as being an exempt school contribution if the contribution is made pursuant to a Federal capital contribution from such payments.

(6) REPORTS BY SCHOOLS.—Each agreement under section 721 with a school of medicine or osteopathic medicine shall provide that the school will submit to the Secretary a report for each 1-year period under paragraph (1) that provides such information as the Secretary determines to be necessary for carrying out this subsection. Each such report shall include statistics concerning the current training or practice status of all graduates of such school whose date of graduation from the

school occurred approximately 4 years before the end of the 1-year period involved.

(c) **REPORTS BY SECRETARY.**—The Secretary shall each fiscal year submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report regarding the administration of this section, including the extent of compliance with the requirements of this section, during the preceding fiscal year.

(d) **DEFINITIONS.**—For purposes of this section:

(1) The term “exempt contributions” means exempt Federal capital contributions and exempt school contributions.

(2) The term “exempt Federal capital contribution” means a Federal capital contribution described in subclause (I) of subsection (a)(2)(A)(ii).

(3) The term “exempt school contribution” means a school contribution described in subclause (II) of subsection (a)(2)(A)(ii).

(4) The term “income”, with respect to a student fund under section 721, means payments of principal and interest on any loan made from the fund, and any other earnings of the fund.

(5) The term “primary health care” means family medicine, general internal medicine, general pediatrics, preventive medicine, or osteopathic general practice.

SEC. 724. [292t] INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS.

(a) **FUND AGREEMENTS REGARDING CERTAIN AMOUNTS.**—With respect to amounts appropriated under subsection (f), each agreement entered into under section 721 with a school shall provide (in addition to the provisions required in subsection (b) of such section) that—

(1) any Federal capital contribution made to the student loan fund of the school from such amounts, together with the school contribution appropriate under subsection (b)(2)(B) of such section to the amount of the Federal capital contribution, will be utilized only for the purpose of—

(A) making loans to individuals from disadvantaged backgrounds; and

(B) the costs of the collection of the loans and interest on the loans; and

(2) collections of principal and interest on loans made pursuant to paragraph (1), and any other earnings of the student loan fund attributable to amounts that are in the fund pursuant to such paragraph, will be utilized only for the purpose described in such paragraph.

(b) **MINIMUM QUALIFICATIONS FOR SCHOOLS.**—The Secretary may not make a Federal capital contribution for purposes of subsection (a) for a fiscal year unless the health professions school involved—

(1) is carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including racial and ethnic minorities; and

(2) is carrying out a program for recruiting and retaining minority faculty.

(c) CERTAIN AGREEMENTS REGARDING EDUCATION OF STUDENTS; DATE CERTAIN FOR COMPLIANCE.—The Secretary may not make a Federal capital contribution for purposes of subsection (a) for a fiscal year unless the health professions school involved agrees—

(1) to ensure that adequate instruction regarding minority health issues is provided for in the curricula of the school;

(2) with respect to health clinics providing services to a significant number of individuals who are from disadvantaged backgrounds, including members of minority groups, to enter into arrangements with 1 or more such clinics for the purpose of providing students of the school with experience in providing clinical services to such individuals;

(3) with respect to public or nonprofit private secondary educational institutions and undergraduate institutions of higher education, to enter into arrangements with 1 or more such institutions for the purpose of carrying out programs regarding the educational preparation of disadvantaged students, including minority students, to enter the health professions and regarding the recruitment of such individuals into the health professions;

(4) to establish a mentor program for assisting disadvantaged students, including minority students, regarding the completion of the educational requirements for degrees from the school;

(5) to be carrying out each of the activities specified in any of paragraphs (1) through (4) by not later than 1 year after the date on which the first Federal capital contribution is made to the school for purposes of subsection (a); and

(6) to continue carrying out such activities, and the activities specified in paragraphs (1) and (2) of subsection (b), throughout the period during which the student loan fund established pursuant to section 721(b) is in operation.

(d) AVAILABILITY OF OTHER AMOUNTS.—With respect to Federal capital contributions to student loan funds under agreements under section 721(b), any such contributions made before October 1, 1990, together with the school contributions appropriate under paragraph (2)(B) of such section to the amount of the Federal capital contributions, may be utilized for the purpose of making loans to individuals from disadvantaged backgrounds, subject to section 723(a)(2)(B).

(e) DEFINITION.—For purposes of this section, the term “disadvantaged”, with respect to an individual, shall be defined by the Secretary.

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—With respect to making Federal capital contributions to student loan funds for purposes of subsection (a), there is authorized to be appropriated for such contributions \$15,000,000 for fiscal year 1993.

(2) SPECIAL CONSIDERATION FOR CERTAIN SCHOOLS.—In making Federal capital contributions to student loan funds for purposes of subsection (a), the Secretary shall give special consideration to health professions schools that have enrollments

of underrepresented minorities above the national average for health professions schools.

SEC. 725. [292u] ADMINISTRATIVE PROVISIONS.

The Secretary may agree to modifications of agreements or loans made under this subpart, and may compromise, waive, or release any right, title, claim, or demand of the United States arising or acquired under this subpart.

SEC. 726. [292v] PROVISION BY SCHOOLS OF INFORMATION TO STUDENTS.

(a) **IN GENERAL.**—With respect to loans made by a school under this subpart after June 30, 1986, each school, in order to carry out the provisions of sections 721 and 722, shall, at any time such school makes such a loan to a student under this subpart, provide thorough and adequate loan information on loans made under this subpart to the student. The loan information required to be provided to the student by this subsection shall include—

(1) the yearly and cumulative maximum amounts that may be borrowed by the student;

(2) the terms under which repayment of the loan will begin;

(3) the maximum number of years in which the loan must be repaid;

(4) the interest rate that will be paid by the borrower and the minimum amount of the required monthly payment;

(5) the amount of any other fees charged to the borrower by the lender;

(6) any options the borrower may have for deferral, cancellation, prepayment, consolidation, or other refinancing of the loan;

(7) a definition of default on the loan and a specification of the consequences which will result to the borrower if the borrower defaults, including a description of any arrangements which may be made with credit bureau organizations;

(8) to the extent practicable, the effect of accepting the loan on the eligibility of the borrower for other forms of student assistance; and

(9) a description of the actions that may be taken by the Federal Government to collect the loan, including a description of the type of information concerning the borrower that the Federal Government may disclose to (A) officers, employees, or agents of the Department of Health and Human Services, (B) officers, employees, or agents of schools with which the Secretary has an agreement under this subpart, or (C) any other person involved in the collection of a loan under this subpart.

(b) **STATEMENT REGARDING LOAN.**—Each school shall, immediately prior to the graduation from such school of a student who receives a loan under this subpart after June 30, 1986, provide such student with a statement specifying—

(1) each amount borrowed by the student under this subpart;

(2) the total amount borrowed by the student under this subpart; and

(3) a schedule for the repayment of the amounts borrowed under this subpart, including the number, amount, and frequency of payments to be made.

SEC. 727. [292w] PROCEDURES FOR APPEAL OF TERMINATION OF AGREEMENTS.

In any case in which the Secretary intends to terminate an agreement with a school under this subpart, the Secretary shall provide the school with a written notice specifying such intention and stating that the school may request a formal hearing with respect to such termination. If the school requests such a hearing within 30 days after the receipt of such notice, the Secretary shall provide such school with a hearing conducted by an administrative law judge.

SEC. 728. [292x] DISTRIBUTION OF ASSETS FROM LOAN FUNDS.

(a) **DISTRIBUTION AFTER TERMINATION OF FUND.**—If a school terminates a loan fund established under an agreement pursuant to section 721(b), or if the Secretary for good cause terminates the agreement with the school, there shall be a capital distribution as follows:

(1) The Secretary shall first be paid an amount which bears the same ratio to such balance in such fund on the date of termination of the fund as the total amount of the Federal capital contributions to such fund by the Secretary pursuant to section 721(b)(2)(A) bears to the total amount in such fund derived from such Federal capital contributions and from funds deposited therein pursuant to section 721(b)(2)(B).

(2) The remainder of such balance shall be paid to the school.

(b) **PAYMENT OF PROPORTIONATE SHARE TO SECRETARY.**—If a capital distribution is made under subsection (a), the school involved shall, after the capital distribution, pay to the Secretary, not less often than quarterly, the same proportionate share of amounts received by the school in payment of principal or interest on loans made from the loan fund established pursuant to section 721(b) as was determined by the Secretary under subsection (a).

SEC. 735. [292y] GENERAL PROVISIONS.

(a) **DATE CERTAIN FOR APPLICATIONS.**—The Secretary shall from time to time set dates by which schools must file applications for Federal capital contributions.

(b) **CONTINGENT REDUCTION IN ALLOTMENTS.**—If the total of the amounts requested for any fiscal year in such applications exceeds the amounts appropriated under this section for that fiscal year, the allotment to the loan fund of each such school shall be reduced to whichever of the following is the smaller: (A) the amount requested in its application; or (B) an amount which bears the same ratio to the amounts appropriated as the number of students estimated by the Secretary to be enrolled in such school during such fiscal year bears to the estimated total number of students in all such schools during such year. Amounts remaining after allotment under the preceding sentence shall be reallocated in accordance with clause (B) of such sentence among schools whose applications requested more than the amounts so allotted to their loan funds, but with such adjustments as may be necessary to prevent

the total allotted to any such school's loan fund from exceeding the total so requested by it.

(c) **ALLOTMENT OF EXCESS FUNDS.**—Funds available in any fiscal year for payment to schools under this subpart which are in excess of the amount appropriated pursuant to this section for that year shall be allotted among schools in such manner as the Secretary determines will best carry out the purposes of this subpart.

(d) **PAYMENT OF INSTALLMENTS TO SCHOOLS.**—Allotments to a loan fund of a school shall be paid to it from time to time in such installments as the Secretary determines will not result in unnecessary accumulations in the loan fund at such school.

(e) **DISPOSITION OF FUNDS RETURNED TO SECRETARY.**—

(1) **EXPENDITURE FOR FEDERAL CAPITAL CONTRIBUTIONS.**—Subject to section 723(b)(5), any amounts from student loan funds under section 721 that are returned to the Secretary by health professions schools shall be expended to make Federal capital contributions to such funds.

(2) **DATE CERTAIN FOR CONTRIBUTIONS.**—Amounts described in paragraph (1) that are returned to the Secretary before the fourth quarter of a fiscal year shall be obligated before the end of such fiscal year, and may not be obligated before the fourth quarter. For purposes of the preceding sentence, amounts returned to the Secretary during the last quarter of a fiscal year are deemed to have been returned during the first three quarters of the succeeding fiscal year.

(3) **PREFERENCE IN MAKING CONTRIBUTIONS.**—In making Federal capital contributions to student loans funds under section 721 for a fiscal year from amounts described in paragraph (1), the Secretary shall give preference to health professions schools of the same disciplines as the health professions schools returning such amounts for the period during which the amounts expended for such contributions were received by the Secretary. Any such amounts that, prior to being so returned, were available only for the purpose of loans under this subpart to individuals from disadvantaged backgrounds shall be available only for such purpose.

(f) **FUNDING FOR CERTAIN MEDICAL SCHOOLS.**—

(1) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of making Federal capital contributions to student loan funds established under section 721 by schools of medicine or osteopathic medicine, there is authorized to be appropriated \$10,000,000 for each of the fiscal years 1994 through 1996.

(2) **MINIMUM REQUIREMENTS.**—

(A) Subject to subparagraph (B), the Secretary may make a Federal capital contribution pursuant to paragraph (1) only if the school of medicine or osteopathic medicine involved meets the conditions described in subparagraph (A) of section 723(b)(2) or the conditions described in subparagraph (C) of such section.

(B) For purposes of subparagraph (A), the conditions referred to in such subparagraph shall be applied with respect to graduates of the school involved whose date of graduation occurred approximately 3 years before June 30

of the fiscal year preceding the fiscal year for which the Federal capital contribution involved is made.

PART B—STUDENTS FROM DISADVANTAGED BACKGROUNDS

SEC. 736. [293] SCHOLARSHIPS FOR STUDENTS OF EXCEPTIONAL FINANCIAL NEED.

(a) **IN GENERAL.**—The Secretary shall make grants to public and nonprofit private schools of medicine, osteopathic medicine, and dentistry for scholarships to be awarded by the schools to full-time students thereof who are of exceptional financial need, subject to section 795 (relating to residency training and practice in primary health care).

(b) **REQUIREMENTS REGARDING SCHOLARSHIPS.**—

(1) **ACCEPTANCE FOR FULL-TIME ENROLLMENT.**—Scholarships may be awarded by a school from a grant under subsection (a) only to individuals who have been accepted by it for enrollment as full-time students.

(2) **AUTHORIZED EXPENDITURES.**—A scholarship provided to a student for a school year under a grant under subsection (a) shall consist of payment to, or (in accordance with paragraph (4)) on behalf of, the student of an amount (except as provided in section 798(c)) equivalent to the amount of—

(A) the tuition of the student in such school year; and

(B) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the student in such year.

(3) **AUTHORITY REGARDING PAYMENTS TO EDUCATIONAL INSTITUTION.**—The Secretary may contract with an educational institution in which is enrolled a student who has received a scholarship with a grant under subsection (a) for the payment to the educational institution of the amounts of tuition and other reasonable educational expenses described in paragraph (2). Payment to such an educational institution may be made without regard to section 3324 of title 31, United States Code.

(c) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of making grants under this section, there is authorized to be appropriated \$11,000,000 for fiscal year 1993.

SEC. 737. [293a] SCHOLARSHIPS GENERALLY; CERTAIN OTHER PURPOSES.

(a) **ESTABLISHMENT OF PROGRAM.**—

(1) **IN GENERAL.**—Subject to subsection (e), the Secretary may make grants to health professions schools for the purpose of assisting such schools in providing scholarships to individuals described in paragraph (2).

(2) **ELIGIBLE INDIVIDUALS.**—The individuals referred to in paragraph (1) are individuals who—

(A) are from disadvantaged backgrounds; and

(B) are enrolled (or accepted for enrollment) as full-time students in such schools.

(3) **HEALTH PROFESSIONS SCHOOLS.**—For purposes of this section, the term “health professions schools” means schools of

medicine, nursing (as schools of nursing are defined in section 853), osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, veterinary medicine, public health, or allied health, or schools offering graduate programs in clinical psychology.

(b) **MINIMUM QUALIFICATIONS OF GRANTEES.**—The Secretary may not make a grant under subsection (a) unless the health professions school—

(1) is carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including racial and ethnic minorities; and

(2) is carrying out a program for recruiting and retaining minority faculty.

(c) **PREFERENCES IN PROVIDING SCHOLARSHIPS.**—The Secretary may not make a grant under subsection (a) unless the health professions school involved agrees that, in providing scholarships pursuant to the grant, the school will give preference to students—

(1) who are from disadvantaged backgrounds; and

(2) for whom the costs of attending the school would constitute a severe financial hardship.

(d) **USE OF SCHOLARSHIP.**—A scholarship provided pursuant to subsection (a) for attendance at a health professions school—

(1) may be expended only for tuition expenses, other reasonable educational expenses, and reasonable living expenses incurred in such attendance; and

(2) may not, for any year of such attendance for which the scholarship is provided, provide an amount exceeding the total amount required for the year for the expenses specified in paragraph (1).

(e) **PROVISIONS REGARDING PURPOSES OTHER THAN SCHOLARSHIPS.**—

(1) **AUTHORITY REGARDING ASSISTANCE FOR UNDERGRADUATES.**—With respect to undergraduates who have demonstrated a commitment to pursuing a career in the health professions, a health professions school may expend not more than 25 percent of a grant under subsection (a) for the purpose of providing financial assistance to such undergraduates in order to facilitate the completion of the educational requirements for such careers.

(2) **REQUIRED ACTIVITIES OF SCHOOL.**—The Secretary may not make a grant under subsection (a) unless the health professions school involved agrees—

(A) to ensure that adequate instruction regarding minority health issues is provided for in the curricula of the school;

(B) with respect to health clinics providing services to a significant number of individuals who are from disadvantaged backgrounds, including members of minority groups, to enter into arrangements with 1 or more such clinics for the purpose of providing students of the school with experience in providing clinical services to such individuals;

(C) with respect to public or nonprofit secondary educational institutions and undergraduate institutions of higher education, to enter into arrangements with 1 or

more such institutions for the purpose of carrying out programs regarding the educational preparation of disadvantaged students, including minority students, to enter the health professions and regarding the recruitment of such students into the health professions;

(D) to establish a mentor program for assisting disadvantaged students, including minority students, regarding the completion of the educational requirements for degrees from the school;

(E) to be carrying out the activities specified in subparagraphs (A) through (D) by not later than 1 year after the date on which a grant under subsection (a) is first made to the school; and

(F) to continue carrying out such activities, and the activities specified in paragraphs (1) and (2) of subsection (b), throughout the period during which the school is receiving a grant under subsection (a).

(3) RESTRICTIONS ON USE OF GRANT.—The Secretary may not make a grant under subsection (a) for a fiscal year unless the health professions school involved agrees that the grant will not be expended to carry out the activities specified in paragraph (1) or (2) of subsection (b), or in any of subparagraphs (A) through (D) of paragraph (2) of this subsection.

(f) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(g) DEFINITION.—For purposes of this section, the term “school of nursing” has the meaning given such term in section 853.

(h) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for fiscal year 1993.

(2) ALLOCATIONS BY SECRETARY.—In making grants under subsection (a), the Secretary—

(A) shall, of the amounts appropriated under paragraph (1), make available 30 percent for such grants to schools of nursing; and

(B) shall give special consideration to health professions schools that have enrollments of underrepresented minorities above the national average for health professions schools.

SEC. 738. [293b] LOAN REPAYMENTS AND FELLOWSHIPS REGARDING FACULTY POSITIONS.

(a) LOAN REPAYMENTS.—

(1) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program of entering into contracts with individuals described in subsection (b) under which the individuals agree to serve as members of the faculties of schools described in paragraph (3) in consideration of the Federal Government agreeing to pay, for each year of such service, not more than

\$20,000 of the principal and interest of the educational loans of such individuals.

(2) **ELIGIBLE INDIVIDUALS.**—The individuals referred to in paragraph (1) are individuals from disadvantaged backgrounds who—

(A) have a degree in medicine, osteopathic medicine, dentistry, or another health profession;

(B) are enrolled in an approved graduate training program in medicine, osteopathic medicine, dentistry, or other health profession; or

(C) are enrolled as a full-time student—

(i) in an accredited (as determined by the Secretary) school described in paragraph (3); and

(ii) in the final year of a course of a study or program, offered by such institution and approved by the Secretary, leading to a degree from such a school.

(3) **ELIGIBLE HEALTH PROFESSIONS SCHOOLS.**—The schools described in this paragraph are schools of medicine, nursing (as schools of nursing are defined in section 853), osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, veterinary medicine, or public health, or schools offering graduate programs in clinical psychology.

(4) **ADDITIONAL LIMITATION ON AMOUNT OF REPAYMENTS.**—Payments made under this subsection regarding the educational loans of an individual may not, for any year for which the payments are made, exceed an amount equal to 20 percent of the outstanding principal and interest on the loans.

(5) **REQUIREMENTS REGARDING FACULTY POSITIONS.**—The Secretary may not enter into a contract under paragraph (1) unless—

(A) the individual involved has entered into a contract with a school described in paragraph (3) to serve as a member of the faculty of the school for not less than 2 years, and the individual has not been a member of the faculty of any school at any time during the 18-month period preceding the date on which the Secretary receives the request of the individual for a contract under paragraph (1); and

(B) the contract referred to in subparagraph (A) provides that—

(i) the school will, for each year for which the individual will serve as a member of the faculty under the contract with the school, make payments of the principal and interest due on the educational loans of the individual for such year in an amount equal to the amount of such payments made by the Secretary for the year; and

(ii) the payments made by the school pursuant to clause (i) on behalf of the individual will be in addition to the pay that the individual would otherwise receive for serving as a member of such faculty.

(6) **WAIVER REGARDING SCHOOL CONTRIBUTIONS.**—The Secretary may waive the requirement established in paragraph (5)(B) if the Secretary determines that the requirement will

impose an undue financial hardship on the school involved. If the Secretary grants such a waiver, paragraph (4) shall not apply with respect to the individual involved.

(7) **APPLICABILITY OF CERTAIN PROVISIONS.**—The provisions of sections 338B, 338C, and 338E shall apply to the program established in paragraph (1) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, including the applicability of provisions regarding reimbursements for increased tax liability and regarding bankruptcy.

(b) **FELLOWSHIPS.**—

(1) **IN GENERAL.**—The Secretary may make grants to and enter into contracts with schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, health administration, clinical psychology, and other public or private nonprofit health or educational entities of the type described in section 799, to assist such schools in increasing the number of underrepresented minority faculty members at such schools.

(2) **APPLICATIONS.**—To be eligible to receive a grant or contract under this subsection, a school shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including an assurance that—

(A) amounts received under such a grant or contract will be used to award a fellowship to an individual only if—

(i) the individual has not been a member of the faculty of any school at any time during the 18-month period preceding the date on which the individual submits a request for the fellowship; and

(ii) the individual meets the requirements of paragraphs (3) and (4); and

(B) each fellowship awarded pursuant to the grant or contract will include a stipend in an amount not exceeding 50 percent of the regular salary of a similar faculty member, or \$30,000, whichever is less.

(3) **ELIGIBILITY.**—To be eligible to receive a grant or contract under paragraph (1), an applicant shall demonstrate to the Secretary that such applicant has or will have the ability to—

(A) identify, recruit and select individuals from underrepresented minorities in health professions who have the potential for teaching, administration, or conducting research at a health professions institution;

(B) provide such individuals with the skills necessary to enable them to secure a tenured faculty position at such institution, which may include training with respect to pedagogical skills, program administration, the design and conduct of research, grants writing, and the preparation of articles suitable for publication in peer reviewed journals;

(C) provide services designed to assist such individuals in their preparation for an academic career, including the provision of mentors; and

(D) provide health services to rural or medically underserved populations.

(4) REQUIREMENTS.—To be eligible to receive a grant or contract under paragraph (1) an applicant shall—

(A) provide an assurance that such applicant will make available (directly through cash donations) \$1 for every \$1 of Federal funds received under this section for the fellowship;

(B) provide an assurance that institutional support will be provided for the individual for a second year at a level that is not less than the total amount of Federal and institutional funds provided in the year in which the grant or contract was awarded;

(C) provide an assurance that the individual that will receive the fellowship will be a member of the faculty of the applicant school; and

(D) provide an assurance that the individual that will receive the fellowship will have, at a minimum, appropriate advanced preparation (such as a master's or doctoral degree) and special skills necessary to enable such individual to teach and practice.

(5) DEFINITION.—For purposes of this subsection, the term "minority" means an individual from a racial or ethnic group that is underrepresented in the health professions.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$4,000,000 for fiscal year 1993.

SEC. 739. [293c] CENTERS OF EXCELLENCE.

(a) IN GENERAL.—The Secretary shall make grants to health professions schools described in subsection (c) for the purpose of assisting the schools in supporting programs of excellence in health professions education for minority individuals.

(b) REQUIRED USE OF FUNDS.—The Secretary may not make a grant under subsection (a) unless the health professions school involved agrees to expend the grant—

(1) to establish, strengthen, or expand programs to enhance the academic performance of minority students attending the school;

(2) to establish, strengthen, or expand programs to increase the number and quality of minority applicants to the school;

(3) to improve the capacity of such school to train, recruit, and retain minority faculty;

(4) with respect to minority health issues, to carry out activities to improve the information resources and curricula of the school and clinical education at the school; and

(5) to facilitate faculty and student research on health issues particularly affecting minority groups.

(c) CENTERS OF EXCELLENCE.—

(1) IN GENERAL.—

(A) The health professions schools referred to in subsection (a) are such schools that meet each of the conditions specified in subparagraph (B), and that—

(i) meet each of the conditions specified in paragraph (2)(A);

(ii) meet each of the conditions specified in paragraph (3);

(iii) meet each of the conditions specified in paragraph (4); or

(iv) meet each of the conditions specified in paragraph (5).

(B) The conditions specified in this subparagraph are that a health professions school—

(i) has a significant number of minority individuals enrolled in the school, including individuals accepted for enrollment in the school;

(ii) has been effective in assisting minority students of the school to complete the program of education and receive the degree involved;

(iii) has been effective in recruiting minority individuals to attend the school, including providing scholarships and other financial assistance to such individuals and encouraging minority students of secondary educational institutions to attend the health professions school; and

(iv) has made significant recruitment efforts to increase the number of minority individuals serving in faculty or administrative positions at the school.

(C) In the case of any criteria established by the Secretary for purposes of determining whether schools meet the conditions described in subparagraph (B), this section may not, with respect to racial and ethnic minorities, be construed to authorize, require, or prohibit the use of such criteria in any program other than the program established in this section.

(2) CENTERS OF EXCELLENCE AT CERTAIN HISTORICALLY BLACK COLLEGES AND UNIVERSITIES.—

(A) The conditions specified in this subparagraph are that a health professions school—

(i) is a school described in section 799(1); and

(ii) received a contract under section 788B for fiscal year 1987, as such section was in effect for such fiscal year.

(B) In addition to the purposes described in subsection (b), a grant under subsection (a) to a health professions school meeting the conditions described in subparagraph (A) may be expended—

(i) to develop a plan to achieve institutional improvements, including financial independence, to enable the school to support programs of excellence in health professions education for minority individuals; and

(ii) to provide improved access to the library and informational resources of the school.

(3) **HISPANIC CENTERS OF EXCELLENCE.**—The conditions specified in this paragraph are that—

(A) with respect to Hispanic individuals, each of clauses (i) through (iv) of paragraph (1)(B) applies to the health professions school involved; and

(B) the health professions school agree, as a condition of receiving a grant under subsection (a), that the school will, in carrying out the duties described in subsection (b), give priority to carrying out the duties with respect to Hispanic individuals.

(4) **NATIVE AMERICAN CENTERS OF EXCELLENCE.**—Subject to subsection (e), the conditions specified in this paragraph are that—

(A) with respect to Native Americans, each of clauses (i) through (iv) of paragraph (1)(B) applies to the health professions school involved;

(B) the health professions school agree, as a condition of receiving a grant under subsection (a), that the school will, in carrying out the duties described in subsection (b), give priority to carrying out the duties with respect to Native Americans; and

(C) the health professions school agree, as a condition of receiving a grant under subsection (a), that—

(i) the school will establish an arrangement with 1 or more public or nonprofit private institutions of higher education whose enrollment of students has traditionally included a significant number of Native Americans, the purpose of which arrangement will be to carry out a program—

(I) to identify Native American students of the institution who are interested in a career in the health profession or professions involved; and

(II) to facilitate the educational preparation of such students to enter the health professions school; and

(ii) the health professions school will make efforts to recruit Native American students, including students who have participated in the undergraduate program carried out under arrangements established by the school pursuant to clause (i) and will assist Native American students regarding the completion of the educational requirements for a degree from the health professions school.

(5) **OTHER CENTERS OF EXCELLENCE.**—The conditions specified in this paragraph are that a health professions school has an enrollment of underrepresented minorities above the national average for such enrollments of health professions schools.

(d) **DESIGNATION AS CENTER OF EXCELLENCE.**—

(1) **IN GENERAL.**—Any health professions school receiving a grant under subsection (a) and meeting the conditions described in paragraph (2) or (5) of subsection (c) shall, for purposes of this section, be designated by the Secretary as a Center of Excellence in Minority Health Professions Education.

(2) **HISPANIC CENTERS OF EXCELLENCE.**—Any health professions school receiving a grant under subsection (a) and meeting the conditions described in subsection (c)(3) shall, for purposes of this section, be designated by the Secretary as a Hispanic Center of Excellence in Health Professions Education.

(3) **NATIVE AMERICAN CENTERS OF EXCELLENCE.**—Any health professions school receiving a grant under subsection (a) and meeting the conditions described in subsection (c)(4) shall, for purposes of this section, be designated by the Secretary as a Native American Center of Excellence in Health Professions Education. Any consortium receiving such a grant pursuant to subsection (e) shall, for purposes of this section, be so designated.

(e) **AUTHORITY REGARDING NATIVE AMERICAN CENTERS OF EXCELLENCE.**—

(1) **AUTHORITY FOR COLLECTIVELY MEETING RELEVANT REQUIREMENTS.**—With respect to meeting the conditions specified in subsection (c)(4), the Secretary may make a grant under subsection (a) to any school of medicine, osteopathic medicine, dentistry, or pharmacy that has in accordance with paragraph (2) formed a consortium of schools that meets such conditions (without regard to whether the schools of the consortium individually meet such conditions).

(2) **REQUIREMENTS REGARDING CONSORTIUM.**—A consortium of schools has been formed in accordance with this paragraph if—

(A) the consortium consists of a school seeking a grant pursuant to paragraph (1) and 1 or more schools of medicine, osteopathic medicine, dentistry, pharmacy, nursing, allied health, or public health;

(B) the schools of the consortium have entered into an agreement for the allocation of such grant among the schools;

(C) each of the schools agrees to expend the grant in accordance with this section; and

(D) each of the schools of the consortium—

(i) is part of the same institution of higher education as the school seeking the grant; or

(ii) is located not farther than 50 miles from the school seeking the grant.

(f) **DURATION AND AMOUNT OF GRANT.**—

(1) **DURATION.**—The period during which payments are made under a grant under subsection (a) may not exceed 3 years. Such payments shall be subject to annual approval by the Secretary and to the availability of appropriations for the fiscal year involved to make the payments.

(2) **AMOUNT.**—A grant under subsection (a) for a fiscal year may not be made in an amount that is less than \$500,000.

(g) **MAINTENANCE OF EFFORT.**—

(1) **IN GENERAL.**—With respect to activities for which a grant under subsection (a) is authorized to be expended, the Secretary may not make such a grant to a health professions school for any fiscal year unless the school agrees to maintain expenditures of non-Federal amounts for such activities at a

level that is not less than the level of such expenditures maintained by the school for the fiscal year preceding the fiscal year for which the school receives such a grant.

(2) **USE OF FEDERAL FUNDS.**—With respect to any Federal amounts received by a health professions school and available for carrying out activities for which a grant under subsection (a) is authorized to be expended, the Secretary may not make such a grant to the school for any fiscal year unless the school agrees that the school will, before expending the grant, expend the Federal amounts obtained from sources other than the grant.

(h) **DEFINITIONS.**—For purposes of this section:

(1)(A) The term “health professions school” means, except as provided in subparagraph (B), a school of medicine, a school of osteopathic medicine, a school of dentistry, or a school of pharmacy.

(B) The definition established in subparagraph (A) shall not apply to the use of the term “health professions school” for purposes of subsection (c)(2).

(2) The term “program of excellence” means any program carried out by a health professions school with a grant made under subsection (a), if the program is for purposes for which the school involved is authorized in subsection (b) or (c) to expend the grant.

(3) The term “Native Americans” means American Indians, Alaskan Natives, Aleuts, and Native Hawaiians.

(i) **FUNDING.**—

(1) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of making grants under subsection (a), there are authorized to be appropriated such sums as may be necessary for fiscal year 1993.

(2) **ALLOCATIONS BY SECRETARY.**—

(A) Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary shall make available \$12,000,000 for grants under subsection (a) to health professions schools that are eligible for such grants pursuant to meeting the conditions described in paragraph (2)(A) of subsection (c).

(B) Of the amounts appropriated under paragraph (1) for a fiscal year and available after compliance with subparagraph (A), the Secretary shall make available 60 per cent for grants under subsection (a) to health professions schools that are eligible for such grants pursuant to meeting the conditions described in paragraph (3) or (4) of subsection (c) (including meeting conditions pursuant to subsection (e)).

(C) Of the amounts appropriated under paragraph (1) for a fiscal year and available after compliance with subparagraph (A), the Secretary shall make available 40 per cent for grants under subsection (a) to health professions schools that are eligible for such grants pursuant to meeting the conditions described in paragraph (5) of subsection (c).

SEC. 740. [293d] EDUCATIONAL ASSISTANCE REGARDING UNDERGRADUATES.**(a) IN GENERAL.—**

(1) **AUTHORITY FOR GRANTS.**—For the purpose of assisting individuals from disadvantaged backgrounds, as determined in accordance with criteria prescribed by the Secretary, to undertake education to enter a health profession, the Secretary may make grants to and enter into contracts with schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, chiropractic, and podiatric medicine, public and nonprofit private schools which offer graduate programs in clinical psychology, and other public or private nonprofit health or educational entities to assist in meeting the costs described in paragraph (2).

(2) **AUTHORIZED EXPENDITURES.**—A grant or contract under paragraph (1) may be used by the health or educational entity to meet the cost of—

(A) identifying, recruiting, and selecting individuals from disadvantaged backgrounds, as so determined, for education and training in a health profession,

(B) facilitating the entry of such individuals into such a school,

(C) providing counseling or other services designed to assist such individuals to complete successfully their education at such a school,

(D) providing, for a period prior to the entry of such individuals into the regular course of education of such a school, preliminary education designed to assist them to complete successfully such regular course of education at such a school, or referring such individuals to institutions providing such preliminary education,

(E) publicizing existing sources of financial aid available to students in the education program of such a school or who are undertaking training necessary to qualify them to enroll in such a program,

(F) paying such scholarships as the Secretary may determine for such individuals for any period of health professions education at a school of medicine, osteopathic medicine, or dentistry,

(G) paying such stipends as the Secretary may approve for such individuals for any period of education in student-enhancement programs (other than regular courses) at any school described in subsection (a)(1), except that such a stipend may not be provided to an individual for more than 12 months, and such a stipend shall be in an amount of \$40 per day (notwithstanding any other provision of law regarding the amount of stipends).

The term "regular course of education of such a school" as used in subparagraph (D) includes a graduate program in clinical psychology.

(b) REQUIREMENTS REGARDING ENROLLMENT; PRIORITY IN MAKING GRANTS.—

(1) **INCREASED ENROLLMENT OF INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS.**—Schools of medicine, osteopathic

medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, chiropractic, podiatric medicine and public and nonprofit schools that offer graduate programs in clinical psychology that receive a grant under subsection (a) shall, during a period of 3 years commencing on the date of the award of the grant, increase their first year enrollments of individuals from disadvantaged backgrounds by at least 20 percent over enrollments in the base year 1987.

(2) **CONDITIONS FOR SCHOOLS TO RECEIVE PRIORITY.**—The Secretary shall give priority for funding, in years subsequent to the expiration of the 3-year period described in paragraph (1)—

(A) to schools that attain such increase in their first year enrollment by the end of such 3-year period, and

(B) to schools that attain a 20 percent increase over such base year enrollment.

(3) **APPLICABILITY OF CERTAIN CONDITION FOR PRIORITY.**—The requirement for at least a 20 percent increase in such enrollment shall apply only to those schools referred to in paragraph (1) that have a proportionate enrollment of such individuals from disadvantaged backgrounds that is less than 200 percent of the national average percentage of such individuals in all schools of each health professions discipline.

(4) **DETERMINATION OF ENROLLMENT.**—Determination of both first year and total enrollment of such individuals shall be made by the Secretary in accordance with section 792.

(c) **EQUITABLE ALLOCATION OF FINANCIAL ASSISTANCE.**—The Secretary shall ensure that services and activities under subsection (a) are equitably allocated among the various racial and ethnic populations.

(d) **FUNDING.**—

(1) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of grants and contracts under subsection (a)(1), there is authorized to be appropriated \$31,500,000 for fiscal year 1993.

(2) **ALLOCATIONS.**—Of the amounts appropriated under paragraph (1) for any fiscal year, the Secretary shall obligate amounts in accordance with the following:

(A) 70 percent shall be obligated for grants or contracts to institutions of higher education.

(B) 20 percent shall be obligated for scholarships under subsection (a)(2)(F) to individuals of exceptional financial need (as defined by the Secretary under section 736) who are students at schools of medicine, osteopathic medicine, or dentistry. The provision of such scholarships to such individuals shall be subject to section 795 (relating to residency training and practice in primary health care). Such scholarships shall be administered and awarded in the same manner and subject to the same requirements as scholarships under section 736.

(C) 10 percent shall be obligated for community-based programs.

(D) Not more than 5 percent may be obligated for grants and contracts having the primary purpose of in-

forming individuals about the existence and general nature of health careers.

PART C—TRAINING IN PRIMARY HEALTH CARE

SEC. 746. [293j] AREA HEALTH EDUCATION CENTER PROGRAMS.

(a) AUTHORITY FOR PROVISION OF FINANCIAL ASSISTANCE.—

(1) ASSISTANCE FOR PLANNING, DEVELOPMENT, AND OPERATION OF PROGRAMS.—

(A) The Secretary shall provide financial assistance to schools of medicine and osteopathic medicine for the planning, development, and operation of area health education center programs.

(B)(i) Subject to clause (ii), the period during which payments are made from an award under subparagraph (A) may not exceed 12 years. The provision of the payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments. The preceding sentence may not be construed as establishing a limitation on the number of awards under such subparagraph that may be made to the school involved.

(ii) In the case of an area health education center planned, developed, or operated with an award under subparagraph (A), the period during which the award is expended for the center may not exceed 6 years.

(2) ASSISTANCE FOR CERTAIN PROJECTS OF EXISTING PROGRAMS.—

(A) The Secretary shall provide financial assistance to schools of medicine and osteopathic medicine—

(i) which have previously received Federal financial assistance for an area health education center program under section 802 of the Health Professions Educational Assistance Act of 1976 in fiscal year 1979 or under paragraph (1), or

(ii) which are receiving assistance under paragraph (1),
to carry out projects described in subparagraph (B) through area health education centers for which Federal financial assistance was provided under paragraph (1) and which are no longer eligible to receive such assistance.

(B) Projects for which assistance may be provided under subparagraph (A) are—

(i) projects to improve the distribution, supply, quality, utilization, and efficiency of health personnel in the health services delivery system;

(ii) projects to encourage the regionalization of educational responsibilities of the health professions schools; and

(iii) projects designed to prepare, through preceptorships and other programs, individuals subject to a

service obligation under the National Health Service Corps Scholarship Program to effectively provide health services in health professional shortage areas.

(C) In the case of the requirement established in section 3804(e)(1) of part 57 of title 42, Code of Federal Regulations (42 CFR 57.3804(e)(1)) (relating to the location of area health education centers), the Secretary shall waive such requirement with respect to an area health education center having, at the time of initial application for financial assistance under this section or under a previous authorizing law, an operating program supported by both appropriations of a State legislature and local resources.

(3) ASSISTANCE FOR OPERATION OF MODEL PROGRAMS.—

(A) In the case of any school of medicine or osteopathic medicine that is operating an area health education center program and that is not receiving financial assistance under paragraph (1), the Secretary may provide financial assistance to the school for the costs of operating the program, and for carrying out activities described in subparagraph (E), if the school makes the agreements described in subparagraphs (B) through (D).

(B)(i) For purposes of subparagraph (A), the agreement described in this subparagraph for a school is that, with respect to the costs of operating the area health education center program of the school, the school will make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount that is not less than 50 percent of such costs.

(ii) Amounts provided by the Federal Government may not be included in determining the amount of non-Federal contributions in cash made for purposes of the requirement established in clause (i).

(C) For purposes of subparagraph (A), the agreement described in this subparagraph for a school is that, in operating the area health education program of the school, the school will—

(i) coordinate the activities of the program with the activities of any office of rural health established by the State or States in which the program is operating;

(ii) conduct health professions education and training activities consistent with national and State priorities in the area served by the program in coordination with the National Health Service Corps, entities receiving funds under section 329 or 330, and public health departments; and

(iii) cooperate with any entities that are in operation in the area served by the program and that receive Federal or State funds to carry out activities regarding the recruitment and retention of health care providers.

(D) For purposes of subparagraph (A), the agreement described in this subparagraph for a school is that, with

respect to the costs of operating the area health education center program of the school, the school will maintain expenditures of non-Federal amounts for such costs at a level that is not less than the level of such expenditures maintained by the school for the fiscal year preceding the first fiscal year for which the school receives an award under subparagraph (A).

(E) A school may expend not more than 10 percent of an award under subparagraph (A) for demonstration projects for any or all of the following purposes:

(i) The establishment of computer-based information programs or telecommunication networks that will link health science centers and service delivery sites.

(ii) The provision of disease specific educational programs for health providers and students in areas of concern to the United States.

(iii) The development of information dissemination models to make available new information and technologies emerging from biological research centers to the practicing medical community.

(iv) The institution of new minority recruitment and retention programs, targeted to improved service delivery in areas the program determines to be medically underserved.

(v) The establishment of programs to place physicians from health manpower shortage areas into similar areas to encourage retention of physicians and to provide flexibility to States in filling positions in health professional shortage areas.

(vi) The establishment or improvement of education and training programs for State emergency medical systems.

(vii) The establishment of programs to train health care providers in the identification and referral of cases of domestic violence.

(F) The aggregate amount of awards provided under subparagraph (A) to schools in a State for a fiscal year may not exceed the lesser of—

(i) \$2,000,000; and

(ii) an amount equal to the product of \$250,000 and the aggregate number of area health education centers operated in the State by the schools.

(b) STRUCTURE OF PROGRAMS.—

(1) **IN GENERAL.**—An area health education center program shall be a cooperative program of one or more medical (M.D. and D.O.) schools and one or more nonprofit private or public area health education centers.

(2) **CERTAIN REQUIREMENTS.**—With respect to an area health education center program, a school may not receive an award under paragraph (1) of subsection (a) for operational expenses, or an award under paragraph (2) or (3) of such subsection, unless the program—

(A) maintains preceptorship educational experiences for health science students;

(B) maintains community-based primary care residency programs or is affiliated with such programs;

(C) maintains continuing education programs for health professionals or coordinates with such programs;

(D) maintains learning resource and dissemination systems for information identification and retrieval;

(E) has agreements with community-based organizations for the delivery of education and training in the health professions;

(F) is involved in the training of health professionals (including nurses and allied health professionals), except to the extent inconsistent with the law of the State in which the training is conducted; and

(G) carries out recruitment programs for the health science professions, or programs for health-career awareness, among minority and other elementary or secondary students from areas the program has determined to be medically underserved.

(c) **REQUIREMENTS FOR SCHOOLS.**—Each medical (M.D. and D.O.) school participating in an area health education center program shall—

(1) provide for the active participation in such program by individuals who are associated with the administration of the school and each of the departments (or specialties if the school has no such departments) of internal medicine, pediatrics, obstetrics and gynecology, surgery, psychiatry, and family medicine;

(2) provide that no less than 10 percent of all undergraduate medical (M.D. and D.O.) clinical education of the school will be conducted in an area health education center and at locations under the sponsorship of such center;

(3) be responsible for, or conduct, a program for the training of physician assistants (as defined in section 799) or nurse practitioners (as defined under section 822) which gives special consideration to the enrollment of individuals from, or intending to practice in, the area served by the area health education center of the program; and

(4) provide for the active participation of at least 2 schools or programs of other health professions (including a school of dentistry and a graduate program of mental health practice if there are ones affiliated with the university with which the school of medicine or osteopathic medicine is affiliated) in the educational program conducted in the area served by the area health education center.

The requirement of paragraph (3) shall not apply to a medical (M.D. and D.O.) school participating in an area health education center program if another such school participating in the same program meets the requirement of that paragraph.

(d) **REQUIREMENTS FOR CENTERS.**—

(1) **SERVICE AREA.**—Each area health education center shall specifically designate a geographic area in which it will serve, or shall specifically designate a medically underserved

population it will serve (such area or population with respect to such center in this section referred to as "the area served by the center"), which area or population is in a location remote from the main site of the teaching facilities of the school or schools which participate in the program with such center.

(2) OTHER REQUIREMENTS.—Each area health education center shall—

(A) provide for or conduct training in health education services, including education in nutrition evaluation and counseling, in the area served by the center;

(B) assess the health manpower needs of the area served by the center and assist in the planning and development of training programs to meet such needs;

(C) provide for or conduct a rotating osteopathic internship or a medical residency training program in family medicine, general internal medicine, or general pediatrics in which no fewer than four individuals are enrolled in first-year positions in such program;

(D) provide opportunities for continuing medical education (including education in disease prevention) to all physicians and other health professionals (including allied health personnel) practicing within the area served by the center;

(E) provide continuing medical education and other educational support services to the National Health Service Corps members serving within the area served by the center;

(F) conduct interdisciplinary training and practice involving physicians and other health personnel including, where practicable, physician assistants, nurse practitioners, and nurse midwives;

(G) arrange and support educational opportunities for medical and other students at health facilities, ambulatory care centers, and health agencies throughout the area served by the center; and

(H) have an advisory board of which at least 75 percent of the members shall be individuals, including both health service providers and consumers, from the area served by the center.

Any area health education center which is participating in an area health education center program in which another center has a medical residency training program described in subparagraph (C) need not provide for or conduct such a medical residency training program.

(e) CERTAIN PROVISIONS REGARDING FUNDING.—

(1) PROGRAMS.—Subject to paragraph (2), in providing financial assistance under this section to a school, the Secretary shall assure that—

(A) at least 75 percent of the total funds provided to the school are expended by an area health education center program in the area health education centers, and that the school enters into an agreement with each of such centers for purposes of specifying the allocation of such 75 percent;

(B) with respect to the operating costs of the area health education program of the school, non-Federal contributions for such costs are made in an amount that is not less than 25 percent of such costs; and

(C) no award provides funds solely for the planning or development of such a program for a period exceeding two years.

The Secretary may vest in entities which have received financial assistance under section 802 of the Health Professions Educational Assistance Act of 1976, section 774 as in effect before October 1, 1977, or under subsection (a) of this section for area health education centers programs title to any property acquired on behalf of the United States by that entity (or furnished to that entity by the United States) under that award.

(2) CENTERS.—With respect to the period during which an area health education center is planned, developed or operated pursuant to an award under subsection (a)(1), not more than 55 percent of the total amounts expended for the center in any fifth or sixth year of such period may be provided by the Secretary, subject to paragraph (3).

(3) APPLICABILITY OF PROVISION REGARDING CENTERS.—Paragraph (2) shall apply only in the case of an area health education center program for which the initial award under subsection (a)(1) is provided on or after the date of the enactment of the Health Professions Education Extension Amendments of 1992.

(f) HEALTH EDUCATION AND TRAINING CENTERS.—

(1) IN GENERAL.—The Secretary shall provide financial assistance to schools of medicine and osteopathic medicine for the purpose of planning, developing, establishing, maintaining, and operating health education and training centers—

(A) to improve the supply, distribution, quality, and efficiency of personnel providing health services in the State of Florida or (in the United States) along the border between the United States and Mexico;

(B) to improve the supply, distribution, quality, and efficiency of personnel providing, in other urban and rural areas (including frontier areas) of the United States, health services to any population group, including Hispanic individuals, that has demonstrated serious unmet health care needs; and

(C) to encourage health promotion and disease prevention through public education in the areas described.

(2) ARRANGEMENTS WITH OTHER ENTITIES.—The Secretary may not provide financial assistance under paragraph (1) unless the applicant for such assistance agrees, in carrying out the purpose described in such paragraph, to enter into arrangements with one or more public or nonprofit private entities in the State that have expertise in providing health education to the public.

(3) SERVICE AREA.—The Secretary shall, after consultation with health education and training centers, designate the geographic area in which each such center will carry out the purpose described in paragraph (1). The service area of such a cen-

ter shall be located entirely within the State in which the center is located. Each border health education and training center shall be located in a county (or other political subdivision) of the State in close proximity to the border between the United States and Mexico.

(4) **ADVISORY GROUP; OPERATIONAL PLAN.**—The Secretary may not provide financial assistance under paragraph (1) unless the applicant for such assistance agrees—

(A) to establish an advisory group comprised of health service providers, educators and consumers from the service area and of faculty from participating schools;

(B) after consultation with such advisory group, to develop a plan for carrying out the purpose described in paragraph (1) in the service area;

(C) to enter into contracts, as needed, with other institutions or entities to carry out such plan; and

(D) to be responsible for the evaluation of the program.

(5) **CERTAIN ACTIVITIES.**—The Secretary may not provide financial assistance under paragraph (1) unless the applicant for such assistance agrees—

(A) to evaluate the specific service needs for health care personnel in the service area;

(B) to assist in the planning, development, and conduct of training programs to meet the needs identified pursuant to subparagraph (A);

(C) to conduct or support not less than one training and education program for physicians and one program for nurses for at least a portion of the clinical training of such students;

(D) to conduct or support training in health education services, including training to prepare community health workers to implement health education programs in communities, health departments, health clinics, and public schools that are located in the service area;

(E) to conduct or support continuing medical education programs for physicians and other health professionals (including allied health personnel) practicing in the service area;

(F) to support health career educational opportunities designed to provide students residing in the service area with counseling, education, and training in the health professions;

(G) with respect to border health education and training centers, to assist in coordinating its activities and programs carried out pursuant to paragraph (1)(A) with any similar programs and activities carried out in Mexico along the border between the United States and Mexico;

(H) to make available technical assistance in the service area in the aspects of health care organization, financing and delivery; and

(I) in the case of any school of public health located in the service area of the health education and training center operated with the assistance, to permit any such school

to participate in the program of the center if the school makes a request to so participate.

(6) ALLOCATION OF FUNDS BY CENTERS.—In carrying out this subsection, the Secretary shall ensure that—

(A) not less than 75 percent of the total funds provided to a school or schools of medicine or osteopathic medicine will be expended in the development and operation of the health education and training center in the service area of such program;

(B) to the maximum extent feasible, the school of medicine or osteopathic medicine will obtain from nongovernmental sources the amount of the total operating funds for such program which are not provided by the Secretary;

(C) no award shall provide funds solely for the planning or development of a health education and training center program for a period in excess of two years;

(D) not more than 10 percent of the annual budget of each program may be utilized for the renovation and equipping of clinical teaching sites; and

(E) no award shall provide funds to be used outside the United States except as the Secretary may prescribe for travel and communications purposes related to the conduct of a border health education and training center.

(7) DEFINITIONS.—For purposes of this subsection:

(A) The term "border health education and training center" means an entity that is a recipient of an award under paragraph (1) and that is carrying out (or will carry out) the purpose described in subparagraph (A) of such paragraph.

(B) The term "health education and training center" means an entity that is a recipient of an award under paragraph (1).

(C) The term "service area" means, with respect to a health education and training center, the geographic area designated for the center under paragraph (3).

(8) ALLOCATION OF FUNDS BY SECRETARY.—

(A) Of the amounts appropriated pursuant to subsection (i)(2) for a fiscal year, the Secretary shall make available 50 percent for allocations each fiscal year for applications approved by the Secretary for border health education and training centers. The amount of the allocation for each such center shall be determined in accordance with subparagraph (B).

(B) The amount of an allocation under subparagraph (A) for a fiscal year shall be determined in accordance with a formula prescribed by the Secretary, which formula shall be based—

(i) with respect to the service area of the border health education and training center involved, on the low-income population, including Hispanic individuals, in the State of Florida and along the border between the United States and Mexico, and the growth rate of such population;

(ii) on the need of such population for additional personnel to provide health care services along such border; and

(iii) on the most current information concerning mortality and morbidity and other indicators of health status for such population.

(g) DEFINITIONS.—For purposes of this section:

(1) The term “area health education center program” means a program which is organized as provided in subsection (b) and under which the participating medical (M.D. and D.O.) schools and the area health education centers meet the requirements of subsections (c) and (d).

(2) The term “award” means an award of financial assistance.

(3) The term “financial assistance” means a grant, cooperative agreement, or contract.

(h) CRITERIA AND STANDARDS.—The Secretary shall establish standards and criteria for the requirements of this section.

(i) AUTHORIZATION OF APPROPRIATIONS.—

(1) AREA HEALTH EDUCATION CENTER PROGRAMS.—

(A) For the purpose of carrying out this section other than subsection (f), there is authorized to be appropriated \$25,000,000 for each of the fiscal years 1993 through 1995.

(B) Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may not obligate more than 20 percent for awards under subsection (a)(2).

(C) Of the amounts appropriated under paragraph (1) for fiscal year 1993, the Secretary shall obligate for awards under subsection (a)(3) such amounts as are appropriated in excess of \$19,200,000. Of the amounts appropriated under paragraph (1) for each of the fiscal years 1994 and 1995, the Secretary shall obligate for such awards such amounts as are appropriated in excess of \$18,700,000.

(2) HEALTH EDUCATION AND TRAINING CENTERS.—For the purpose of carrying out subsection (f), there is authorized to be appropriated \$5,000,000 for each of the fiscal years 1993 through 1995.

SEC. 747. [293k] FAMILY MEDICINE.

(a) TRAINING GENERALLY.—The Secretary may make grants to, or enter into contracts with, any public or nonprofit private hospital, school of medicine or osteopathic medicine, or to or with a public or private nonprofit entity (which the Secretary has determined is capable of carrying out such grant or contract)—

(1) to plan, develop, and operate, or participate in, an approved professional training program (including an approved residency or internship program) in the field of family medicine for medical (M.D. and D.O.) students, interns (including interns in internships in osteopathic medicine), residents, or practicing physicians;

(2) to provide financial assistance (in the form of traineeships and fellowships) to medical (M.D. and D.O.) students, interns (including interns in internships in osteopathic medicine), residents, practicing physicians, or other medical

personnel, who are in need thereof, who are participants in any such program, and who plan to specialize or work in the practice of family medicine;

(3) to plan, develop, and operate a program for the training of physicians who plan to teach in family medicine training programs; and

(4) to provide financial assistance (in the form of traineeships and fellowships) to physicians who are participants in any such program and who plan to teach in a family medicine training program.

(b) ACADEMIC ADMINISTRATIVE UNITS.—

(1) IN GENERAL.—The Secretary may make grants to or enter into contracts with schools of medicine or osteopathic medicine to meet the costs of projects to establish, maintain, or improve academic administrative units (which may be departments, divisions, or other units) to provide clinical instruction in family medicine.

(2) PREFERENCE IN MAKING AWARDS.—In making awards of grants and contracts under paragraph (1), the Secretary shall give preference to any qualified applicant for such an award that agrees to expend the award for the purpose of—

(A) establishing an academic administrative unit for programs in family medicine; or

(B) substantially expanding the programs of such a unit.

(c) DURATION OF AWARD.—The period during which payments are made to an entity from an award of a grant or contract under subsection (a) may not exceed 5 years. The provision of such payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments.

(d) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$54,000,000 for each of the fiscal years 1993 through 1995.

(2) ALLOCATION.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary shall make available not less than 20 percent for awards of grants and contracts under subsection (b).

SEC. 748. [2931] GENERAL INTERNAL MEDICINE AND GENERAL PEDIATRICS.

(a) IN GENERAL.—The Secretary may make grants to and enter into contracts with schools of medicine and osteopathic medicine, public or private nonprofit hospitals, or any other public or private nonprofit entity to meet the costs of projects—

(1) to plan, develop, and operate, or participate in, an approved professional training program (including an approved residency or internship program) in the field of internal medicine or pediatrics for medical (M.D. and D.O.) students, interns (including interns in internships in osteopathic medicine), residents, or practicing physicians, which training program emphasizes training for the practice of general internal medicine

or general pediatrics (as defined by the Secretary in regulations);

(2) to provide financial assistance (in the form of traineeships and fellowships) to medical (M.D. and D.O.) students, interns (including interns in internships in osteopathic medicine), residents, practicing physicians, or other medical personnel, who are in need thereof, who are participants in any such training program, and who plan to specialize in or work in the practice of general internal medicine or general pediatrics;

(3) to plan, develop, and operate a program for the training of physicians who will teach in a general internal medicine or general pediatrics training program; and

(4) which provide financial assistance (in the form of traineeships and fellowships) to physicians who are participants in any such program and who plan to teach in a general internal medicine or general pediatrics training program.

(b) DURATION OF AWARD.—The period during which payments are made to an entity from an award of a grant or contract under subsection (a) may not exceed 5 years. The provision of such payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$25,000,000 for each of the fiscal years 1993 through 1995.

SEC. 749. [293m] GENERAL PRACTICE OF DENTISTRY.

(a) IN GENERAL.—The Secretary may make grants to, and enter into contracts with, any public or nonprofit private school of dentistry or accredited postgraduate dental training institution—

(1) to plan, develop, and operate an approved residency program in the general practice of dentistry or an approved advanced educational program in the general practice of dentistry;

(2) to provide financial assistance (in the form of traineeships and fellowships) to participants in such a program who are in need of financial assistance and who plan to specialize in the practice of general dentistry; and

(3) to fund innovative, nontraditional models for the provision of postdoctoral General Dentistry training.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$6,000,000 for each of the fiscal years 1993 through 1995.

SEC. 750. [293n] PHYSICIAN ASSISTANTS.

(a) IN GENERAL.—The Secretary may make grants to and enter into contracts with public or nonprofit private schools of medicine and osteopathic medicine and other public or nonprofit private entities to meet the costs of projects to plan, develop, and operate or maintain programs—

(1) for the training of physician assistants (as defined in section 799); and

(2) for the training of individuals who will teach programs of such training.

(b) **REGULATIONS.**—After consultation with appropriate organizations, the Secretary shall prescribe regulations for programs receiving assistance under subsection (a) for the training of physician assistants. Such regulations shall, as a minimum, require that such a program—

(1) extend for at least one academic year and consist of—

(A) supervised clinical practice; and

(B) at least four months (in the aggregate) of classroom instruction, directed toward preparing students to deliver health care;

(2) have an enrollment of not less than eight students; and

(3) train students in primary care, disease prevention, health promotion, geriatric medicine, and home health care.

(c) **PLACEMENT OF GRADUATES.**—No grant or contract may be made under subsection (a) unless the school or other entity involved provides assurances satisfactory to the Secretary that the school or entity has appropriate mechanisms for placing graduates of the training program with respect to which the application is submitted in positions for which they have been trained.

(d) **FUNDING.**—

(1) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there is authorized to be appropriated \$9,000,000 for each of the fiscal years 1993 through 1995.

(2) **LIMITATION.**—Not more than 10 percent of the amounts appropriated under paragraph (1) may be expended for carrying out subsection (a)(2).

SEC. 751. [293o] PODIATRIC MEDICINE.

(a) **IN GENERAL.**—The Secretary may make grants to, and enter into contracts with, public and nonprofit private hospitals and schools of podiatric medicine for the purpose of planning and implementing projects in primary care training for podiatric physicians in approved or provisionally approved residency programs which shall provide financial assistance in the form of traineeships to residents who participate in such projects and who plan to specialize in primary care.

(b) **PREFERENCE IN MAKING GRANTS.**—In making grants under subsection (a), the Secretary shall give preference to qualified applicants that provide clinical training in podiatric medicine in a variety of medically underserved communities.

(c) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there is authorized to be appropriated \$1,000,000 for each of the fiscal years 1993 through 1995.

SEC. 752. [293p] GENERAL PROVISIONS.

(a) **TRAINEESHIPS AND FELLOWSHIPS.**—

(1) **TRAINEESHIPS.**—Payments by recipients of grants or contracts under this part for traineeships shall be limited to such amounts as the Secretary finds necessary to cover the cost of tuition and fees of, and stipends and allowances (including travel and subsistence expenses and dependency allowances) for the trainees.

(2) **FELLOWSHIPS.**—Payments by recipients of grants or contracts under this part for fellowships shall be limited to

such amounts as the Secretary finds necessary to cover the cost of advanced study by, and stipends and allowances (including travel and subsistence expenses and dependency allowances) for, the fellows.

(b) AMOUNT OF GRANT.—The amount of any grant or contract under this part shall be determined by the Secretary.

PART D—TRAINING IN CERTAIN HEALTH PROFESSIONS

Subpart I—Public Health and Preventive Medicine

SEC. 761. [294] PUBLIC HEALTH TRAINEESHIPS.

(a) IN GENERAL.—The Secretary may make grants to accredited schools of public health, and to other public or nonprofit private institutions accredited for the provision of graduate or specialized training in public health, for the purpose of assisting such schools and institutions in providing traineeships to individuals described in subsection (b)(3).

(b) CERTAIN REQUIREMENTS.—

(1) APPLICATION FOR GRANT.—No grant for traineeships may be made under subsection (a) unless an application therefor has been submitted to, and approved by, the Secretary. Such application shall be in such form, be submitted in such manner, and contain such information, as the Secretary by regulation may prescribe. Traineeships under such a grant shall be awarded in accordance with such regulations as the Secretary shall prescribe. The amount of any such grant shall be determined by the Secretary.

(2) USE OF GRANT.—Traineeships awarded under grants made under subsection (a) shall provide for tuition and fees and such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the trainees as the Secretary may deem necessary.

(3) ELIGIBLE INDIVIDUALS.—The individuals referred to in subsection (a) are individuals who are pursuing a course of study in a health professions field in which there is a severe shortage of health professionals (which fields include the fields of epidemiology, environmental health, biostatistics, toxicology, nutrition, and maternal and child health).

SEC. 762. [294a] PUBLIC HEALTH SPECIAL PROJECTS.

(a) IN GENERAL.—The Secretary may make grants to and enter into contracts with accredited schools of public health for the costs of planning, developing, demonstrating, operating, and evaluating projects that are in furtherance of the goals established by the Secretary for the year 2000 in the area of—

- (1) preventive medicine;
- (2) health promotion and disease prevention;
- (3) improving access to and quality of health services in medically underserved communities; or
- (4) reducing the incidence of domestic violence.

(b) **PREFERENCES IN MAKING AWARDS.**—In making awards of grants and contracts under subsection (a), the Secretary shall give preference to qualified schools agreeing that the project for which the award is made—

(1) will establish or strengthen field placements for students in public or nonprofit private health agencies or organizations; and

(2) will involve faculty members and students in collaborative projects to enhance public health services to medically underserved communities.

(c) **PARTICIPATION AND TRAINING OF STUDENTS.**—The Secretary may make an award of a grant or contract under subsection (a) only if the school involved agrees that the students of the school will, through participation in the project for which the award is made, receive training in the activities carried out by the project.

(d) **APPLICATION FOR AWARD.**—The Secretary may make an award of a grant or contract under subsection (a) only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(e) **ESTABLISHMENT OF GOALS; RELATED REPORTS.**—

(1) **GOALS.**—

(A) The Secretary shall establish goals for projects under subsection (a) (including goals regarding the training of students), and shall require that, as a condition of the receipt of grants and contracts under such subsection, schools carry out activities in furtherance of meeting the goals.

(B) The Secretary shall establish and implement a methodology for measuring the extent of progress that has been made toward the goals established under subparagraph (A) by schools receiving grants or contracts under subsection (a).

(2) **REPORTS.**—Not later than February 1, 1994, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report describing the progress made by projects under subsection (a) during the preceding fiscal years toward the goals established under paragraph (1). For purposes of the report, the extent of such progress shall be measured through the methodology established under subparagraph (B) of such paragraph.

SEC. 763. [294b] PREVENTIVE MEDICINE; DENTAL PUBLIC HEALTH.

(a) **IN GENERAL.**—The Secretary may make grants to and enter into contracts with schools of medicine, osteopathic medicine, public health, and dentistry to meet the costs of projects—

(1) to plan and develop new residency training programs and to maintain or improve existing residency training programs in preventive medicine and dental public health; and

(2) to provide financial assistance to residency trainees enrolled in such programs.

(b) **ADMINISTRATION.**—

(1) AMOUNT.—The amount of any grant under subsection (a) shall be determined by the Secretary.

(2) APPLICATION.—No grant may be made under subsection (a) unless an application therefor is submitted to and approved by the Secretary. Such an application shall be in such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe.

(3) ELIGIBILITY.—To be eligible for a grant under subsection (a), the applicant must demonstrate to the Secretary that it has or will have available full-time faculty members with training and experience in the fields of preventive medicine or dental public health and support from other faculty members trained in public health and other relevant specialties and disciplines.

(4) OTHER FUNDS.—Schools of medicine, osteopathic medicine, dentistry, and public health may use funds committed by State, local, or county public health officers as matching amounts for Federal grant funds for residency training programs in preventive medicine.

SEC. 765. [294c] AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For the purpose of carrying out this subpart, there is authorized to be appropriated \$15,500,000 for each of the fiscal years 1993 through 1995.

(b) LIMITATION REGARDING CERTAIN PROGRAM.—In obligating amounts appropriated under subsection (a), the Secretary may not obligate more than 40 percent for carrying out section 762.

Subpart II—Allied Health Professions

SEC. 766. [294d] ADVANCED TRAINING.

(a) IN GENERAL.—The Secretary may award grants to and enter into contracts with eligible entities to assist such entities in meeting the costs associated with projects designed to—

(1) plan, develop, establish or expand postbaccalaureate programs for the advanced training of allied health professionals; and

(2) provide financial assistance, in the form of traineeships or fellowships, to postbaccalaureate students who are participants in any such program and who commit to teaching in the allied health profession involved.

(b) PREFERENCE.—In awarding grants under subsection (a), the Secretary shall give preference to qualified projects demonstrating that not less than 50 percent of the graduates of such schools or programs during the preceding 2-year period are engaged as full-time teaching faculty in an allied health shortage specialty.

(c) LIMITATION.—The Secretary shall limit grants and contracts awarded or entered into under subsection (a) to those allied health fields or specialties as the Secretary shall, from time to time, determine to have—

(1) the most significant national or regional shortages of practitioners;

(2) insufficient numbers of qualified faculty in entry level or advanced educational programs; or

(3) a significant role in the care and rehabilitation of patients who are elderly or disabled including physical therapists and occupational therapists.

(d) **ELIGIBLE ENTITIES.**—For purposes of this section, the term “eligible entities” means entities that are—

(1) public or private nonprofit schools, universities, or other educational entities that provide for education and training in the allied health professions and that meet such standards as the Secretary may by regulation prescribe; or

(2) public or nonprofit private entities capable, as determined by the Secretary, of carrying out projects described in subsection (a).

(e) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there is authorized to be appropriated \$5,000,000 for each of the fiscal years 1993 through 1995.

SEC. 767. [294e] PROJECT GRANTS AND CONTRACTS.

(a) **PROJECTS RELATED TO STRENGTHENING TRAINING AND INCREASING ENROLLMENT IN THE ALLIED HEALTH PROFESSIONS.**—The Secretary may make grants to and enter into contracts with eligible entities to assist such entities in meeting the costs associated with expanding or establishing programs that will increase the number of individuals trained in allied health professions. Programs and activities funded under this section may include—

(1) those that expand enrollments in allied health professions with the greatest shortages or whose services are most needed by the elderly;

(2) those that provide rapid transition training programs in allied health fields to individuals who have baccalaureate degrees in health-related sciences;

(3) those that establish community-based allied health training programs that link academic centers to rural clinical settings;

(4) those that provide career advancement training for practicing allied health professionals;

(5) those that expand or establish clinical training sites for allied health professionals in medically underserved or rural communities in order to increase the number of individuals trained;

(6) those that develop curriculum that will emphasize knowledge and practice in the areas of prevention and health promotion, geriatrics, long-term care, home health and hospice care, and ethics;

(7) those that expand or establish interdisciplinary training programs that promote the effectiveness of allied health practitioners in geriatric assessment and the rehabilitation of the elderly;

(8) those that expand or establish demonstration centers to emphasize innovative models to link allied health clinical practice, education, and research; and

(9) those that provide financial assistance (in the form of traineeships) to students who are participants in any such program; and

(A) who plan to pursue a career in an allied health field that has a demonstrated personnel shortage; and

(B) who agree upon completion of the training program to practice in a medically underserved community; that shall be utilized to assist in the payment of all or part of the costs associated with tuition, fees and such other stipends as the Secretary may consider necessary.

(b) APPLICATION.—

(1) REQUIREMENT.—No grant may be awarded or contract entered into under this section unless an application therefore has been submitted to, and approved by, the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe.

(2) PREFERENCE.—In considering an application submitted for a grant under this section, the Secretary shall give preference to qualified applicants that—

(A) expand and maintain first-year enrollment by not less than 10 percent over enrollments in base year 1992; or

(B) demonstrate that not less than 20 percent of the graduates of such training programs during the preceding 2-year period are working in medically underserved communities.

(c) ELIGIBLE ENTITIES.—For purposes of this section, the term “eligible entities” has the meaning given such term in section 766.

(d) AUTHORIZATION OF APPROPRIATION.—For the purpose of carrying out this section, there is authorized to be appropriated \$5,000,000 for each of the fiscal years 1993 through 1995.

Subpart III—Health Administration

SEC. 771. [294i] TRAINEESHIPS AND SPECIAL PROJECTS.

(a) IN GENERAL.—The Secretary may make grants to public or nonprofit private educational entities (including graduate schools of social work but excluding accredited schools of public health) that offer a program described in subsection (b)—

(1) to provide traineeships for students enrolled in such a program; and

(2) to assist programs of health administration in the development or improvement of programs to prepare students for employment with public or nonprofit private entities.

(b) RELEVANT PROGRAMS.—The program referred to in subsection (a) is a program in health administration, hospital administration, or health policy analysis and planning, which program is accredited by a body or bodies approved for such purpose by the Secretary of Education and which meets such other quality standards as the Secretary of Health and Human Services by regulation may prescribe.

(c) PREFERENCE IN MAKING GRANTS.—In making grants under subsection (a), the Secretary shall give preference to qualified applicants that meet the following conditions:

(1) Not less than 25 percent of the graduates of the applicant are engaged in full-time practice settings in medically underserved communities.

(2) The applicant recruits and admits students from medically underserved communities.

(3) For the purpose of training students, the applicant has established relationships with public and nonprofit providers of health care in the community involved.

(4) In training students, the applicant emphasizes employment with public or nonprofit private entities.

(d) CERTAIN PROVISIONS REGARDING TRAINEESHIPS.—

(1) USE OF GRANT.—Traineeships awarded under grants made under subsection (a) shall provide for tuition and fees and such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the trainees as the Secretary may deem necessary.

(2) PREFERENCE FOR CERTAIN STUDENTS.—Each entity applying for a grant under subsection (a) for traineeships shall assure to the satisfaction of the Secretary that the entity will give priority to awarding the traineeships to students who demonstrate a commitment to employment with public or nonprofit private entities in the fields with respect to which the traineeships are awarded.

(e) APPLICATION FOR GRANT.—No grant may be made under subsection (a) unless an application therefor has been submitted to, and approved by, the Secretary. Such application shall be in such form, be submitted in such manner, and contain such information, as the Secretary may prescribe. Traineeships under such a grant shall be awarded in accordance with such requirements as the Secretary shall prescribe. The amount of any such grant shall be determined by the Secretary.

(f) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For payments under grants under subsection (a), there is authorized to be appropriated \$2,500,000 for each of the fiscal years 1993 through 1995.

(2) LIMITATION.—In obligating amounts appropriated under paragraph (1) for a fiscal year, the Secretary may not obligate more than 30 percent for grants under subsection (a)(2).

PART E—SPECIAL TRAINING PROJECTS

SEC. 776. [294n] ACQUIRED IMMUNE DEFICIENCY SYNDROME.

(a) SCHOOLS; CENTERS.—

(1) IN GENERAL.—The Secretary may make grants and enter into contracts to assist public and nonprofit private entities and schools and academic health science centers in meeting the costs of projects—

(A) to train the faculty of schools of, and graduate departments or programs of, medicine, nursing, osteopathic medicine, dentistry, public health, allied health, and mental health practice to teach health professions students to

provide for the health care needs of individuals with HIV disease;

(B) to train practitioners to provide for the health care needs of such individuals;

(C) with respect to improving clinical skills in the diagnosis, treatment, and prevention of such disease, to educate and train the health professionals and clinical staff of schools of medicine, osteopathic medicine, and dentistry; and

(D) to develop and disseminate curricula and resource materials relating to the care and treatment of individuals with such disease and the prevention of the disease among individuals who are at risk of contracting the disease.

(2) PREFERENCE IN MAKING GRANTS.—In making grants under paragraph (1), the Secretary shall give preference to qualified projects which will—

(A) train, or result in the training of, health professionals who will provide treatment for minority individuals with HIV disease and other individuals who are at high risk of contracting such disease; and

(B) train, or result in the training of, minority health professionals and minority allied health professionals to provide treatment for individuals with such disease.

(3) APPLICATION.—No grant or contract may be made under paragraph (1) unless an application is submitted to the Secretary in such form, at such time, and containing such information, as the Secretary may prescribe.

(b) DENTAL SCHOOLS.—

(1) IN GENERAL.—The Secretary may make grants to assist dental schools and programs described in section 777(b)(4)(B) with respect to oral health care to patients with HIV disease.

(2) APPLICATION.—Each dental school or program described in section 777(b)(4)(B) may annually submit an application documenting the unreimbursed costs of oral health care provided to patients with HIV disease by that school or hospital during the prior year.

(3) DISTRIBUTION.—The Secretary shall distribute the available funds among all eligible applicants, taking into account the number of patients with HIV disease served and the unreimbursed oral health care costs incurred by each institution as compared with the total number of patients served and costs incurred by all eligible applicants.

(4) MAINTENANCE OF EFFORT.—The Secretary shall not make a grant under this subsection if doing so would result in any reduction in State funding allotted for such purposes.

(c) DEFINITION.—For purposes of this section:

(1) The term "HIV disease" means infection with the human immunodeficiency virus, and includes any condition arising from such infection.

(2) The term "human immunodeficiency virus" means the etiologic agent for acquired immune deficiency syndrome.

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) SCHOOLS; CENTERS.—For the purpose of grants under subsection (a), there is authorized to be appropriated \$23,000,000 for each of the fiscal years 1993 through 1995.

(2) DENTAL SCHOOLS.—For the purpose of grants under subsection (b), there is authorized to be appropriated \$7,000,000 for each of the fiscal years 1993 through 1995.

SEC. 777. [294o] GERIATRICS.

(a) GERIATRIC EDUCATION CENTERS.—The Secretary may make grants to and enter into contracts with accredited health professions schools or programs described in paragraph (1), (3), or (4) of section 799 or in section 853(2) to assist in meeting the costs of such schools or programs of projects to—

(1) improve the training of health professionals in geriatrics;

(2) develop and disseminate curricula relating to the treatment of the health problems of elderly individuals;

(3) expand and strengthen instruction in methods of such treatment;

(4) support the training and retraining of faculty to provide such instruction;

(5) support continuing education of health professionals and allied health professionals who provide such treatment; and

(6) establish new affiliations with nursing homes, chronic and acute disease hospitals, ambulatory care centers, and senior centers in order to provide students with clinical training in geriatric medicine.

(b) GERIATRIC TRAINING REGARDING PHYSICIANS AND DENTISTS.—

(1) IN GENERAL.—The Secretary may make grants to, and enter into contracts with, schools of medicine, schools of osteopathic medicine, teaching hospitals, and graduate medical education programs, for the purpose of providing support (including residencies, traineeships, and fellowships) for geriatric training projects to train physicians and dentists who plan to teach geriatric medicine, geriatric psychiatry, or geriatric dentistry.

(2) REQUIREMENTS.—Each project for which a grant or contract is made under this subsection shall—

(A) be staffed by full-time teaching physicians who have experience or training in geriatric medicine or geriatric psychiatry;

(B) be staffed, or enter into an agreement with an institution staffed by full-time or part-time teaching dentists who have experience or training in geriatric dentistry;

(C) be based in a graduate medical education program in internal medicine or family medicine or in a department of geriatrics or psychiatry;

(D) provide training in geriatrics and exposure to the physical and mental disabilities of elderly individuals through a variety of service rotations, such as geriatric consultation services, acute care services, dental services, geriatric psychiatry units, day and home care programs,

rehabilitation services, extended care facilities, geriatric ambulatory care and comprehensive evaluation units, and community care programs for elderly mentally retarded individuals; and

(E) provide training in geriatrics through one or both of the training options described in subparagraphs (A) and (B) of paragraph (3).

(3) TRAINING OPTIONS.—The training options referred to in subparagraph (F) of paragraph (2) shall be as follows:

(A) A 1-year retraining program in geriatrics for—

(i) physicians who are faculty members in departments of internal medicine, family medicine, gynecology, geriatrics, and psychiatry at schools of medicine and osteopathic medicine; and

(ii) dentists who are faculty members at schools of dentistry or at hospital departments of dentistry.

(B) A 2-year internal medicine or family medicine fellowship program providing emphasis in geriatrics, which shall be designed to provide training in clinical geriatrics and geriatrics research for—

(i) physicians who have completed graduate medical education programs in internal medicine, family medicine, psychiatry, neurology, gynecology, or rehabilitation medicine; and

(ii) dentists who have demonstrated a commitment to an academic career and who have completed postdoctoral dental training, including postdoctoral dental education programs or who have relevant advanced training or experience.

(4) DEFINITIONS.—For purposes of this subsection:

(A) The term “graduate medical education program” means a program sponsored by a school of medicine, a school of osteopathic medicine, a hospital, or a public or private institution that—

(i) offers postgraduate medical training in the specialties and subspecialties of medicine; and

(ii) has been accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association through its Committee on Postdoctoral Training.

(B) The term “post-doctoral dental education program” means a program sponsored by a school of dentistry, a hospital, or a public or private institution that—

(i) offers post-doctoral training in the specialties of dentistry, advanced education in general dentistry, or a dental general practice residency; and

(ii) has been accredited by the Commission on Dental Accreditation.

(c) GERIATRIC TRAINING REGARDING OPTOMETRISTS.—The Secretary may make grants to, and enter into contracts with, schools and colleges of optometry for the purpose of providing support for projects—

(1) to plan, develop, and operate projects in postgraduate geriatric care training for optometrists who will teach geriatric optometry;

(2) to provide financial assistance (in the form of residencies, traineeships, and fellowships) to participants in such projects; and

(3) to establish new affiliations with nursing homes, ambulatory care centers, senior centers, and other public or non-profit private entities.

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) EDUCATION CENTERS; TRAINING.—For grants and contracts under subsections (a) and (b), there is authorized to be appropriated \$17,000,000 for each of the fiscal years 1993 through 1995.

(2) OPTOMETRY.—For grants and contracts under subsection (c), there is authorized to be appropriated \$400,000 for each of the fiscal years 1993 through 1995.

SEC. 778. [294p] RURAL AREAS.

(a) GRANTS.—The Secretary may make grants to, or enter into contracts with, any eligible applicant to help such applicant fund authorized activities under an application approved under subsection (d).

(b) USE OF AMOUNTS.—

(1) IN GENERAL.—Amounts provided under subsection (a) shall be used by the recipients to fund interdisciplinary training projects designed to—

(A) use new and innovative methods to train health care practitioners to provide services in rural areas;

(B) demonstrate and evaluate innovative interdisciplinary methods and models designed to provide access to cost-effective comprehensive health care;

(C) deliver health care services to individuals residing in rural areas;

(D) enhance the amount of relevant research conducted concerning health care issues in rural areas; and

(E) increase the recruitment and retention of health care practitioners in rural areas and make rural practice a more attractive career choice for health care practitioners.

(2) METHODS.—A recipient of funds under subsection (a) may use various methods in carrying out the projects described in paragraph (1), including—

(A) the distribution of stipends to students of eligible applicants;

(B) the establishment of a post-doctoral fellowship program;

(C) the training of faculty in the economic and logistical problems confronting rural health care delivery systems; or

(D) the purchase or rental of transportation and telecommunication equipment where the need for such equipment due to unique characteristics of the rural area is demonstrated by the recipient.

(3) ADMINISTRATION.—

(A) IN GENERAL.—An applicant shall not use more than 10 percent of the funds made available to such applicant under subsection (a) for administrative expenses.

(B) TRAINING.—Not more than 10 percent of the individuals receiving training with funds made available to an applicant under subsection (a) shall be trained as doctors of medicine or doctors of osteopathy.

(C) LIMITATION.—An institution that receives a grant under this section shall use amounts received under such grant to supplement, not supplant, amounts made available by such institution for activities of the type described in subsection (b)(1) in the fiscal year preceding the year for which the grant is received.

(c) ELIGIBLE APPLICANTS.—Applicants eligible to obtain funds under subsection (a) shall include local health departments, non-profit organizations and public or nonprofit colleges, universities, or schools of, or programs that specialize in, nursing, mental health practice, optometry, public health, dentistry, osteopathy, physicians assistants, pharmacy, podiatry, medicine, chiropractic, and allied health professions if such applicants submit applications approved by the Secretary under subsection (d). Applicants eligible to obtain funds under subsection (a) shall not include for-profit entities, either directly or through a subcontract or subgrant.

(d) APPLICATIONS.—

(1) SUBMISSION.—In order to receive a grant under subsection (a) an entity shall submit an application to the Secretary.

(2) FORMS.—An application submitted under this subsection shall be in such form, be submitted by such date, and contain such information as the Secretary shall require.

(3) APPLICATIONS.—Applications submitted under this subsection shall—

(A) be jointly submitted by at least two eligible applicants with the express purpose of assisting individuals in academic institutions in establishing long-term collaborative relationships with health care providers in rural areas;

(B) designate a rural health care agency or agencies for clinical treatment or training, including hospitals, community health centers, migrant health centers, rural health clinics, community mental health centers, long-term care facilities, Native Hawaiian health centers, or facilities operated by the Indian Health Service or an Indian tribe or tribal organization or Indian organization under a contract with the Indian Health Service under the Indian Self-Determination Act; and

(C) provide any additional information required by the Secretary.

(e) DEFINITIONS.—For the purposes of this section, the term “rural” means geographic areas that are located outside of standard metropolitan statistical areas.

(f) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there is authorized to be appropriated \$7,000,000 for each of the fiscal years 1993 through 1995.

PART F—MISCELLANEOUS PROGRAMS

SEC. 781. [295] RESEARCH ON CERTAIN HEALTH PROFESSIONS ISSUES.

(a) EDUCATIONAL INDEBTEDNESS.—

(1) **IN GENERAL.**—Subject to paragraph (2), the Secretary may make grants to and enter into contracts with public and nonprofit private entities for the purpose of conducting research on the extent to which the debt incurred by medical students for attendance at educational institutions has had a detrimental effect on the decisions made by the students on entering primary care specialties.

(2) **EVALUATION OF RATE OF INCREASE.**—In carrying out paragraph (1), the Secretary shall provide for a determination of the reasons underlying the rate of increase occurring since January 1, 1981, in tuition and fees for attending health professions schools. The Secretary shall ensure that the determination includes the justifications of such schools for such rate.

(b) EFFECT OF PROGRAMS FOR MINORITY AND DISADVANTAGED INDIVIDUALS.—

(1) **IN GENERAL.**—The Secretary may make grants to and enter into contracts with public and nonprofit private entities for the purpose of conducting research on the effects that federally-funded educational programs or policies for minority or disadvantaged individuals have on—

(A) the number of such individuals attending health professions school;

(B) the number of such individuals completing the programs of education involved; and

(C) the decisions made by such individuals on which of the health professions specialties to enter.

(2) **SEPARATE SPECIFICATIONS FOR CERTAIN CATEGORIES OF SCHOOLS.**—The Secretary may provide a grant or contract under paragraph (1) only if the applicant involved agrees that in conducting research under such paragraph the applicant will make findings specific to the following categories of health professions schools:

(A) Health professions schools of historically black colleges and universities.

(B) Other health professions schools attended by a substantial number of minority individuals.

(C) Health professions schools generally.

(c) **EXTENT OF INVESTIGATIONS AND DISCIPLINARY ACTIONS BY STATE LICENSING AUTHORITIES.**—The Secretary may make grants to and enter into contracts with public and nonprofit private entities for the purpose of conducting research on the effectiveness of the States in protecting the public health through—

(1) identifying health care providers with respect to whom investigations of professional qualifications are warranted;

(2) conducting such investigations; and

(3) taking disciplinary actions against health care providers determined through such investigations to have engaged in conduct inconsistent with protecting the public health.

(d) PRIMARY HEALTH CARE.—

(1) IN GENERAL.—The Secretary may make grants to and enter into contracts with public and nonprofit private entities for the purpose of conducting research—

(A) to determine the extent to which Federal programs and related financial incentives influence the percentage of medical school graduates selecting a primary care career;

(B) to determine the extent to which Federal programs and related financial incentives adequately support the training of mid-level primary care providers relative to other health professions education receiving Federal assistance;

(C) to assess the impact that direct and indirect payments for graduate medical education (including the appropriateness of payments for independent, ambulatory training sites) have on increasing the percentage of physicians graduating from medical school who enter primary care careers;

(D) to assess the impact of medical school admission policies on specialty selection and recommend ways admission policies can better facilitate and promote the selection of primary care as a medical career;

(E) to assess the impact that Federal funding for biomedical research influences the design of medical school curriculum and the availability of primary care educational opportunities;

(F) to assess the impact of medical school curriculum, including the availability of clinical training in ambulatory care settings, influences the percentage of physicians selecting primary care residencies and selecting primary care as a medical career; and

(G) to assess the extent to which current physician payment policies under resource based relative value scale are sufficient to encourage physicians graduating from medical school to enter and remain in primary care careers.

(2) DEFINITIONS.—For purposes of this subsection:

(A) The term “primary care careers”, with respect to medicine, means family practice, general internal medicine and general pediatrics.

(B) The term “mid-level primary care health professions” means physician assistants, nurse practitioners, and nurse midwives.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$4,000,000 for each of the fiscal years 1993 through 1995.

SEC. 782. [295a] CHIROPRACTIC DEMONSTRATION PROJECTS.

(a) IN GENERAL.—The Secretary may make grants to and enter into contracts with schools, colleges, and universities of chiropractic

for the purpose of carrying out demonstration projects in which chiropractors and physicians collaborate to identify and provide effective treatment for spinal and lower-back conditions.

(b) **PARTICIPATION OF MEDICAL SCHOOLS.**—The Secretary may make an award of a grant or contract under subsection (a) only if the applicant involved has entered into such agreements as may be necessary to ensure that in the project under such subsection a school of medicine or osteopathic medicine will participate in the project.

(c) **PEER REVIEW.**—Each peer review group under section 798(a) reviewing proposals for grants or contracts under subsection (a) shall include no fewer than two, and no more than three, chiropractors.

(d) **REPORT TO CONGRESS.**—

(1) **IN GENERAL.**—The Secretary shall prepare a report that—

(A) summarizes the applications submitted to the Secretary for grants or contracts under subsection (a);

(B) specifies the identity of entities receiving the grants or contracts; and

(C) evaluates the effectiveness of the programs operated with the grants and contracts.

(2) **DATE CERTAIN FOR SUBMISSION.**—Not later than February 10, 1995, the Secretary shall complete the report required in paragraph (1) and submit the report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

(e) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there is authorized to be appropriated \$1,000,000 for each of the fiscal years 1993 through 1995.

PART G—GENERAL PROVISIONS

SEC. 791. [295j] PREFERENCES AND REQUIRED INFORMATION IN CERTAIN PROGRAMS.

(a) **PREFERENCES IN MAKING AWARDS.**—

(1) **IN GENERAL.**—Subject to paragraph (2), in making awards of grants or contracts under any of sections 747 through 751, under section 763, or under section 766 or 767, the Secretary shall give preference to any qualified applicant that—

(A) has a high rate for placing graduates in practice settings having the principal focus of serving residents of medically underserved communities; or

(B) during the 2-year period preceding the fiscal year for which such an award is sought, has achieved a significant increase in the rate of placing graduates in such settings.

(2) **LIMITATION REGARDING PEER REVIEW.**—For purposes of paragraph (1), the Secretary may not give an applicant preference if the proposal of the applicant is ranked at or below the 20th percentile of proposals that have been recommended for approval by peer review groups under section 798(a).

(b) **REQUIRED SUBMISSION OF INFORMATION.**—The Secretary may make an award of a grant or contract under any of sections 747 through 751 or under section 763, 766, or 767 only if the applicant for the award submits to the Secretary (through the application required in section 798(f)(2)) the following information regarding the programs of the applicant:

(1) A description of rotations or preceptorships for students, or clinical training programs for residents, that have the principal focus of providing health care to medically underserved communities.

(2) The number of faculty on admissions committees who have a clinical practice in community-based ambulatory settings in medically underserved communities.

(3) With respect to individuals who are from disadvantaged backgrounds or from medically underserved communities, the number of such individuals who are recruited for academic programs of the applicant, the number of such individuals who are admitted to such programs, and the number of such individuals who graduate from such programs.

(4) If applicable, the number of recent graduates who have chosen careers in primary health care.

(5) The number of recent graduates whose practices are serving medically underserved communities.

(6) A description of whether and to what extent the applicant is able to operate without Federal assistance under this title.

(c) **DEFINITION.**—For purposes of this section, the term “graduate” means, unless otherwise specified, an individual who has successfully completed all training and residency requirements necessary for full certification in the health profession selected by the individual.

SEC. 792. [295k] HEALTH PROFESSIONS DATA.

(a) **IN GENERAL.**—The Secretary shall establish a program, including a uniform health professions data reporting system, to collect, compile, and analyze data on health professions personnel which program shall initially include data respecting all physicians and dentists in the States. The Secretary is authorized to expand the program to include, whenever he determines it necessary, the collection, compilation, and analysis of data respecting pharmacists, optometrists, podiatrists, veterinarians, public health personnel, audiologists, speech pathologists, health care administration personnel, nurses, allied health personnel, medical technologists, chiropractors, clinical psychologists, and any other health personnel in States designated by the Secretary to be included in the program. Such data shall include data respecting the training, licensure status (including permanent, temporary, partial, limited, or institutional), place or places of practice, professional specialty, practice characteristics, place and date of birth, sex, and socioeconomic background of health professions personnel and such other demographic information regarding health professions personnel as the Secretary may require.

(b) **CERTAIN AUTHORITIES AND REQUIREMENTS.**—

(1) **SOURCES OF INFORMATION.**—In carrying out subsection (a), the Secretary shall collect available information from appropriate local, State, and Federal agencies and other appropriate sources.

(2) **CONTRACTS FOR STUDIES OF HEALTH PROFESSIONS.**—The Secretary shall conduct or enter into contracts for the conduct of analytic and descriptive studies of the health professions, including evaluations and projections of the supply of, and requirements for, the health professions by specialty and geographic location. Such studies shall include studies determining by specialty and geographic location the number of health professionals (including allied health professionals and health care administration personnel) who are members of minority groups, including Hispanics, and studies providing by specialty and geographic location evaluations and projections of the supply of, and requirements for, health professionals (including allied health professionals and health care administration personnel) to serve minority groups, including Hispanics.

(3) **GRANTS AND CONTRACTS REGARDING STATES.**—The Secretary is authorized to make grants and to enter into contracts with States (or an appropriate nonprofit private entity in any State) for the purpose of participating in the program established under subsection (a). The Secretary shall determine the amount and scope of any such grant or contract. To be eligible for a grant or contract under this paragraph a State or entity shall submit an application in such form and manner and containing such information as the Secretary shall require. Such application shall include reasonable assurance, satisfactory to the Secretary, that—

(A) such State (or nonprofit entity within a State) will establish a program of mandatory annual registration of the health professions personnel described in subsection (a) who reside or practice in such State and of health institutions licensed by such State, which registration shall include such information as the Secretary shall determine to be appropriate;

(B) such State or entity shall collect such information and report it to the Secretary in such form and manner as the Secretary shall prescribe; and

(C) such State or entity shall comply with the requirements of subsection (e).

(d)¹ **REPORTS TO CONGRESS.**—The Secretary shall submit to the Congress on October 1, 1993, and biennially thereafter, the following reports:

(1) A comprehensive report regarding the status of health personnel according to profession, including a report regarding the analytic and descriptive studies conducted under this section.

(2) A comprehensive report regarding applicants to, and students enrolled in, programs and institutions for the training of health personnel, including descriptions and analyses of student indebtedness, student need for financial assistance, finan-

¹ So in law. Probably should be redesignated as (c).

cial resources to meet the needs of students, student career choices such as practice specialty and geographic location and the relationship, if any, between student indebtedness and career choices.

(e)¹ REQUIREMENTS REGARDING PERSONAL DATA.—

(1) IN GENERAL.—The Secretary and each program entity shall in securing and maintaining any record of individually identifiable personal data (hereinafter in this subsection referred to as “personal data”) for purposes of this section—

(A) inform any individual who is asked to supply personal data whether he is legally required, or may refuse, to supply such data and inform him of any specific consequences, known to the Secretary or program entity, as the case may be, of providing or not providing such data;

(B) upon request, inform any individual if he is the subject of personal data secured or maintained by the Secretary or program entity, as the case may be, and make the data available to him in a form comprehensible to him;

(C) assure that no use is made of personal data which use is not within the purposes of this section unless an informed consent has been obtained from the individual who is the subject of such data; and

(D) upon request, inform any individual of the use being made of personal data respecting such individual and of the identity of the individuals and entities which will use the data and their relationship to the programs under this section.

(2) CONSENT AS PRECONDITION TO DISCLOSURE.—Any entity which maintains a record of personal data and which receives a request from the Secretary or a program entity for such data for purposes of this section shall not transfer any such data to the Secretary or to a program entity unless the individual whose personal data is to be so transferred gives an informed consent for such transfer.

(3) DISCLOSURE BY SECRETARY.—

(A) Notwithstanding any other provision of law, personal data collected by the Secretary or any program entity under this section may not be made available or disclosed by the Secretary or any program entity to any person other than the individual who is the subject of such data unless (i) such person requires such data for purposes of this section, or (ii) in response to a demand for such data made by means of compulsory legal process. Any individual who is the subject of personal data made available or disclosed under clause (ii) shall be notified of the demand for such data.

(B) Subject to all applicable laws regarding confidentiality, only the data collected by the Secretary under this section which is not personal data shall be made available to bona fide researchers and policy analysts (including the Congress) for the purposes of assisting in the conduct of studies respecting health professions personnel.

¹So in law. Probably should be redesignated as (d).

(4) DEFINITION.—For purposes of this subsection, the term “program entity” means any public or private entity which collects, compiles, or analyzes health professions data under a grant, contract, or other arrangement with the Secretary under this section.

(g)¹ TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to the States and political subdivisions thereof in the development of systems (including model laws) concerning confidentiality and comparability of data collected pursuant to this section.

(h)² GRANTS AND CONTRACTS REGARDING NONPROFIT ENTITIES.—

(1) IN GENERAL.—In carrying out subsection (a), the Secretary may make grants, or enter into contracts and cooperative agreements with, and provide technical assistance to, any nonprofit entity in order to establish a uniform allied health professions data reporting system to collect, compile, and analyze data on the allied health professions personnel.

(2) REPORTS.—With respect to reports required in subsection (d), each such report made on or after October 1, 1991, shall include a description and analysis of data collected pursuant to paragraph (1).

SEC. 793. [2951] STATISTICS; ANNUAL REPORT.

(a) STATISTICS AND OTHER INFORMATION.—The Secretary shall, in coordination with the National Center for Health Statistics (established under section 306), continuously develop, publish, and disseminate on a nationwide basis statistics and other information respecting public and community health personnel, including—

(1) detailed descriptions of the various types of activities in which public and community health personnel are engaged,

(2) the current and anticipated needs for the various types of public and community health personnel, and

(3) the number, employment, geographic locations, salaries, and surpluses and shortages of public and community health personnel, the educational and licensure requirements for the various types of such personnel, and the cost of training such personnel.

(b) REQUIREMENTS REGARDING PERSONAL DATA.—

(1) IN GENERAL.—The Secretary and each program entity shall in securing and maintaining any record of individually identifiable personal data (in this subsection referred to as “personal data”) for purposes of this section—

(A) inform any individual who is asked to supply personal data whether he is legally required, or may refuse, to supply such data and inform him of any specific consequences, known to the Secretary or program entity as the case may be, of providing or not providing such data;

(B) upon request, inform any individual if he is the subject of personal data secured or maintained by the Secretary or program entity, as the case may be, and make the data available to him in a form comprehensible to him;

¹ So in law. Probably should be redesignated as (e).

² So in law. Probably should be redesignated as (f).

(C) assure that no use is made of personal data which is not within the purposes of this section unless an informed consent has been obtained from the individual who is the subject of such data; and

(D) upon request, inform any individual of the use being made of personal data respecting such individual and of the identity of the individuals and entities which will use the data and their relationship to the activities conducted under this section.

(2) CONSENT AS PRECONDITION TO TRANSFER OF INFORMATION.—Any entity which maintains a record of personal data and which receives a request from the Secretary or a program entity to use such data for purposes of this section shall not transfer any such data to the Secretary or to a program entity unless the individual whose personal data is to be so transferred gives an informed consent for such transfer.

(3) DISCLOSURE BY SECRETARY.—

(A) Notwithstanding any other provision of law, personal data collected by the Secretary or any program entity for purposes of this section may not be made available or disclosed by the Secretary or any program entity to any person other than the individual who is the subject of such data unless (i) such person requires such data for purposes of this section, or (ii) in response to a demand for such data made by means of compulsory legal process. Any individual who is the subject of personal data made available or disclosed under clause (ii) shall be notified of the demand for such data.

(B) Subject to all applicable laws regarding confidentiality, only the data collected by the Secretary under this section which is not personal data shall be made available to bona fide researchers and policy analysts (including the Congress) for the purposes of assisting in the conduct of studies respecting health professions personnel.

(4) DEFINITIONS.—For purposes of this subsection, the term "program entity" means any public or private entity which collects, compiles, or analyzes health professions data under an arrangement with the Secretary for purposes of this section.

(c) REPORT.—The Secretary shall submit biennially to the Committee on Energy and Commerce of the House of Representatives and to the Committee on Labor and Human Resources of the Senate a report on—

(1) the statistics and other information developed pursuant to subsection (a); and

(2) the activities conducted under this title, including an evaluation of such activities.

Such report shall contain such recommendations for legislation as the Secretary determines are needed to improve the programs authorized under such subparts. The Office of Management and Budget may review such report before its submission to such Committees, but the Office may not revise the report or delay its submission beyond the date prescribed for its submission and may submit to such Committees its comments respecting such report.

(d) **DEFINITIONS.**—For purposes of this section, the term “public and community health personnel” means individuals who are engaged in—

(1) the planning, development, monitoring, or management of health care or health care institutions, organizations, or systems,

(2) research on health care development and the collection and analysis of health statistics, data on the health of population groups, and any other health data,

(3) the development and improvement of individual and community knowledge of health (including environmental health and preventive medicine) and the health care system, or

(4) the planning and development of a healthful environment and control of environmental health hazards.

SEC. 794. [295m] PROHIBITION AGAINST DISCRIMINATION ON BASIS OF SEX.

The Secretary may not make a grant, loan guarantee, or interest subsidy payment under this title to, or for the benefit of, any school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, pharmacy, podiatric medicine, or public health or any training center for allied health personnel, or graduate program in clinical psychology, unless the application for the grant, loan guarantee, or interest subsidy payment contains assurances satisfactory to the Secretary that the school or training center will not discriminate on the basis of sex in the admission of individuals to its training programs. The Secretary may not enter into a contract under this title with any such school or training center unless the school, training center, or graduate program furnishes assurances satisfactory to the Secretary that it will not discriminate on the basis of sex in the admission of individuals to its training programs. In the case of a school of medicine which—

(1) on the date of the enactment of this sentence is in the process of changing its status as an institution which admits only female students to that of an institution which admits students without regard to their sex, and

(2) is carrying out such change in accordance with a plan approved by the Secretary,

the provisions of the preceding sentences of this section shall apply only with respect to a grant, contract, loan guarantee, or interest subsidy to, or for the benefit of such a school for a fiscal year beginning after June 30, 1979.

SEC. 795. [295n] OBLIGATED SERVICE REGARDING CERTAIN PROGRAMS.

(a) **IN GENERAL.**—In the case of any program under this title under which a scholarship, stipend, or other financial assistance is provided to an individual with respect to education as a health professional (including a program that provides for the repayment of loans), if the program provides that the provision of the financial assistance involved is subject to this section, then the assistance may be provided only if the individual makes agreements as follows:

(1) The individual will complete the program of education with respect to which such assistance is provided (in the case

of assistance provided for purposes other than the repayment of loans).

(2) In the case of an individual who receives such assistance with respect to attendance at a school of medicine or osteopathic medicine, the individual will—

(A) enter and complete a residency training program in a specialty in primary health care not later than 4 years after completing the program of education described in paragraph (1); and

(B) practice in the specialty for 5 years after completing the residency training program.

(3) In the case of an individual who receives such assistance with respect to attendance at a school of dentistry, the individual will practice in general dentistry for 5 years (exclusive of any period during which the individual is attending a residency training program in general dentistry).

(4) Subsection (b) applies with respect to the breach of agreements made under any of paragraphs (1) through (3).

(b) BREACH OF AGREEMENTS.—

(1) IN GENERAL.—For purposes of subsection (a)(4), the following applies:

(A) In the case of a program under this title that provides financial assistance for attendance at a program of education in a health profession, the individual is liable to the Federal Government for the amount of the award (including amounts provided for expenses related to such attendance), and for interest on such amount at the maximum legal prevailing rate, if the individual—

(i) fails to maintain an acceptable level of academic standing in the program of education (as indicated by such program in accordance with requirements established by the Secretary);

(ii) is dismissed from the program for disciplinary reasons; or

(iii) voluntarily terminates the program.

(B) The individual is liable to the Federal Government for the amount of the award (including amounts provided for expenses related to such attendance), and for interest on such amount at the maximum legal prevailing rate, if the individual fails to comply with the agreement made under subsection (a)(2).

(2) WAIVER OR SUSPENSION OF LIABILITY.—In the case of an individual making agreements under subsection (a), the Secretary shall provide for the waiver or suspension of liability under paragraph (1) if compliance by the individual with the agreements involved is impossible, or would involve extreme hardship to the individual, and if enforcement of the agreements with respect to the individual would be unconscionable.

(3) DATE CERTAIN FOR RECOVERY.—Subject to paragraph (2), any amount that the Federal Government is entitled to recover under paragraph (1) shall be paid to the United States not later than the expiration of the three-year period beginning on the date the United States becomes so entitled.

SEC. 798. [295o] CERTAIN GENERAL PROVISIONS.

(a) **PEER REVIEW.**—Each application for a grant or contract under this title shall be submitted to a peer review group for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval. Each peer review group under this subsection shall be composed principally of individuals who are not officers or employees of the Federal Government. This subsection shall be carried out by the Secretary acting through the Administrator of the Health Resources and Services Administration.

(b) **DELEGATION OF AUTHORITY OF SECRETARY.**—The Secretary may delegate the authority to administer any program authorized by this title to the administrator of a central or regional office or offices of the Department, except that the authority to make such a grant, enter into such a contract, continue such a grant or contract, or modify such a contract, shall not be delegated to any administrator of, or officer in, a regional office or offices of the Department.

(c) **DIFFERENTIAL TUITION AND FEES.**—The Secretary may not enter into a contract with, or make a grant, loan guarantee, or interest subsidy payment under this title or title VIII, to or for the benefit of, any school, program, or training center if the tuition levels or educational fees at such school, program, or training center are higher for certain students solely on the basis that such students are the recipients of traineeships, loans, loan guarantees, service scholarships, or interest subsidies from the Federal Government.

(d) **APPLICABILITY OF CERTAIN PROVISIONS ON CONTRACTS.**—Contracts authorized by this title may be entered into without regard to section 3324 of title 31, United States Code, or section 3709 of the Revised Statutes of the United States (41 U.S.C. 5).

(e) **RECORDS AND AUDITS.**—

(1) **MAINTENANCE OF RECORDS.**—

(A) Each entity which receives a grant, loan, loan guarantee, or interest subsidy or which enters into a contract with the Secretary under this title, shall establish and maintain such records as the Secretary shall by regulation or order require.

(B) The Secretary may specify, by regulation, the form and manner in which such records, required by subparagraph (A), shall be established and maintained.

(2) **BIENNIAL AUDITS.**—Each entity which received a grant or entered into a contract under this title shall provide for a biennial financial audit of any books, accounts, financial records, files, and other papers and property which relate to the disposition or use of the funds received under such grant or contract and such other funds received by or allocated to the project or undertaking for which such grant or contract was made. For purposes of assuring accurate, current, and complete disclosure of the disposition or use of the funds received, each such audit shall be conducted in accordance with such requirements concerning the individual or agency which conducts the audit, and such standards applicable to the performance of the

audit, as the Secretary may by regulation provide. A report of each such audit shall be filed with the Secretary at such time and in such manner as he may require.

(3) **APPLICABILITY TO STUDENTS.**—A student recipient of a scholarship, traineeship, loan, or loan guarantee under this title shall not be required to establish or maintain the records required in paragraph (1) or provide for an audit required in paragraph (2).

(4) **AVAILABILITY OF DOCUMENTS, ETC.**—

(A) Each entity which is required to establish and maintain records or to provide for an audit under this subsection shall make such books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of such entity upon a reasonable request therefor.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have the authority to carry out the purposes of this paragraph.

(f) **MISCELLANEOUS PROVISIONS.**—

(1) **PAYMENTS UNDER GRANTS.**—Grants made under this title may be paid (A) in advance or by way of reimbursement, (B) at such intervals and on such conditions as the Secretary may find necessary, and (C) with appropriate adjustments on account of overpayments or underpayments previously made.

(2) **APPLICATIONS FOR GRANTS AND CONTRACTS.**—No grant may be made or contract entered into under this title unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe.

(3) **ASSURANCES.**—Whenever in this title an applicant is required to provide assurances to the Secretary, or an application is required to contain assurances or be supported by assurances, the Secretary shall determine before approving the application that the assurances provided are made in good faith.

(4) **TECHNICAL ASSISTANCE.**—Funds appropriated under this title may be used by the Secretary to provide technical assistance in relation to any of the authorities under this title.

(5) **GRADUATES OF FOREIGN MEDICAL SCHOOLS.**—The Secretary may make an award of a grant, cooperative agreement, or contract under this title to an entity (including a school) that provides graduate training in the health professions only if the entity agrees that, in considering applications for admissions to a program of such training, the entity will not refuse to consider an application solely on the basis that the application is submitted by a graduate of a foreign medical school. This paragraph may not be construed as establishing any private right of action.

SEC. 799. [295p] DEFINITIONS.

For purposes of this title:

(1)(A) The terms "school of medicine", "school of dentistry", "school of osteopathic medicine", "school of pharmacy", "school of optometry", "school of podiatric medicine", "school of veterinary medicine", "school of public health", and "school of chiropractic" mean an accredited public or nonprofit private school in a State that provides training leading, respectively, to a degree of doctor of medicine, a degree of doctor of dentistry or an equivalent degree, a degree of doctor of osteopathy, a degree of bachelor of science in pharmacy or an equivalent degree or a degree of doctor of pharmacy or an equivalent degree, a degree of doctor of optometry or an equivalent degree, a degree of doctor of podiatric medicine or an equivalent degree, a degree of doctor of veterinary medicine or an equivalent degree, a graduate degree in public health or an equivalent degree, and a degree of doctor of chiropractic or an equivalent degree, and including advanced training related to such training provided by any such school.

(B) The terms "graduate program in health administration" and "graduate program in clinical psychology" mean an accredited graduate program in a public or nonprofit private institution in a State that provides training leading, respectively, to a graduate degree in health administration or an equivalent degree and a doctoral degree in clinical psychology or an equivalent degree.

(C) The terms "graduate program in clinical social work" and "graduate program in marriage and family therapy" mean an accredited graduate program in a public or nonprofit private institution in a State that provides training, respectively, in a concentration in health or mental health care leading to a graduate degree in social work and a concentration leading to a graduate degree in marriage and family therapy.

(D) The term "graduate program in mental health practice" means a graduate program in clinical psychology, clinical social work, or marriage and family therapy.

(E) The term "accredited", when applied to a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatry, pharmacy, public health, or chiropractic, or a graduate program in health administration, clinical psychology, clinical social work, or marriage and family therapy, means a school or program that is accredited by a recognized body or bodies approved for such purpose by the Secretary of Education, except that a new school or program that, by reason of an insufficient period of operation, is not, at the time of application for a grant or contract under this title, eligible for accreditation by such a recognized body or bodies, shall be deemed accredited for purposes of this title, if the Secretary of Education finds, after consultation with the appropriate accreditation body or bodies, that there is reasonable assurance that the school or program will meet the accreditation standards of such body or bodies prior to the beginning of the academic year following the normal graduation date of the first entering class in such school or program.

(2) The term "teaching facilities" means areas dedicated for use by students, faculty, or administrative or maintenance personnel for clinical purposes, research activities, libraries, classrooms, offices, auditoriums, dining areas, student activities, or other related purposes necessary for, and appropriate to, the conduct of comprehensive programs of education. Such term includes interim facilities but does not include off-site improvements or living quarters.

(3) The term "program for the training of physician assistants" means an educational program that—

(A) has as its objective the education of individuals who will, upon completion of their studies in the program, be qualified to provide primary health care under the supervision of a physician; and

(B) meets regulations prescribed by the Secretary in accordance with section 750(b).

(4) The term "school of allied health" means a public or nonprofit private college, junior college, or university or hospital-based educational entity that—

(A) provides, or can provide, programs of education to enable individuals to become allied health professionals or to provide additional training for allied health professionals;

(B) provides training for not less than a total of twenty persons in the allied health curricula (except that this subparagraph shall not apply to any hospital-based educational entity);

(C) includes or is affiliated with a teaching hospital; and

(D) is accredited by a recognized body or bodies approved for such purposes by the Secretary of Education, or which provides to the Secretary satisfactory assurance by such accrediting body or bodies that reasonable progress is being made toward accreditation.

(5) The term "allied health professionals" means a health professional (other than a registered nurse or physician assistant)—

(A) who has received a certificate, an associate's degree, a bachelor's degree, a master's degree, a doctoral degree, or postbaccalaureate training, in a science relating to health care;

(B) who shares in the responsibility for the delivery of health care services or related services, including—

(i) services relating to the identification, evaluation, and prevention of disease and disorders;

(ii) dietary and nutrition services;

(iii) health promotion services;

(iv) rehabilitation services; or

(v) health systems management services; and

(C) who has not received a degree of doctor of medicine, a degree of doctor of osteopathy, a degree of doctor of dentistry or an equivalent degree, a degree of doctor of veterinary medicine or an equivalent degree, a degree of doctor of optometry or an equivalent degree, a degree of

doctor of podiatric medicine or an equivalent degree, a degree of bachelor of science in pharmacy or an equivalent degree, a degree of doctor of pharmacy or an equivalent degree, a graduate degree in public health or an equivalent degree, a degree of doctor of chiropractic or an equivalent degree, a graduate degree in health administration or an equivalent degree, a doctoral degree in clinical psychology or an equivalent degree, or a degree in social work or an equivalent degree.

(6) The term "medically underserved community" means an urban or rural area or population that—

(A) is eligible for designation under section 332 as a health professional shortage area;

(B) is eligible to be served by a migrant health center under section 329, a community health center under section 330, a grantee under section 340 (relating to homeless individuals), or a grantee under section 340A (relating to residents of public housing); or

(C) has a shortage of personal health services, as determined under criteria issued by the Secretary under section 1861(aa)(2) of the Social Security Act (relating to rural health clinics).

(7) The term "Department" means the Department of Health and Human Services.

(8) The term "nonprofit" refers to the status of an entity owned and operated by one or more corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(9) The term "State" includes, in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

(10)(A) Subject to subparagraph (B), the term "underrepresented minorities" means, with respect to a health profession, racial and ethnic populations that are underrepresented in the health profession relative to the number of individuals who are members of the population involved.

(B) For purposes of subparagraph (A), Asian individuals shall be considered by the various subpopulations of such individuals.

TITLE VIII—NURSE EDUCATION

PART A—SPECIAL PROJECTS

Subpart I—Special Projects in General

SPECIAL PROJECT GRANTS AND CONTRACTS

SEC. 820. [296k] (a) EXPANSION OF ENROLLMENT IN PROFESSIONAL NURSING PROGRAMS.—

(1) IN GENERAL.—The Secretary may make grants to and enter into contracts with public and nonprofit private schools of nursing with programs of education in professional nursing for the purpose of assisting the schools in increasing the number of students enrolled in such programs. Such a grant or contract may be made only with respect to such programs that are in operation on the date of the enactment of the Health Professions Education Extension Amendments of 1992.

(2) PREFERENCE.—In making awards of grants and contracts under paragraph (1), the Secretary shall give preference to any qualified school that provides students of the school with clinical training in the provision of primary health care in publicly-funded—

(A) urban or rural outpatient facilities, home health agencies, or public health agencies; or

(B) rural hospitals.

(3) MATCHING FUNDS.—

(A) With respect to the costs of the program to be carried out by a school pursuant to paragraph (1), the Secretary may provide an award of a grant or contract under such paragraph only if the school agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that—

(i) for the first fiscal year for which the school receives such an award, is not less than \$1 for each \$9 of Federal funds provided through the award (10 percent of such costs);

(ii) for any second such fiscal year, is not less than \$1 for each \$3 of Federal funds provided through the award (25 percent of such costs);

(iii) for any third such fiscal year, is not less than \$1 for each \$1 of Federal funds provided through the award (50 percent of such costs); and

(iv) for any fourth or fifth such fiscal year, is not less than \$3 for each \$1 of Federal funds provided through the award (75 percent of such costs).

(B) Non-Federal contributions required in subparagraph (A) may be in cash or in kind, fairly evaluated, in-

cluding plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(b) PRIMARY HEALTH CARE IN NONINSTITUTIONAL SETTINGS.—

(1) IN GENERAL.—The Secretary may make grants to and enter into contracts with public and nonprofit private schools of nursing for the establishment or expansion of nursing practice arrangements in noninstitutional settings to demonstrate methods to improve access to primary health care in medically underserved communities.

(2) OPERATION AND STAFFING OF PROGRAMS.—The Secretary may make an award of a grant or contract under paragraph (1) only if the school involved agrees that the program carried out with the award will be operated and staffed by the faculty and students of the school.

(3) DESIGN.—The Secretary may make an award of a grant or contract under paragraph (1) only if the program to be carried out under such paragraph by the school involved is designed to provide at least 25 percent of the students of the school with a structured clinical experience in primary health care.

(c) CONTINUING EDUCATION FOR NURSES IN MEDICALLY UNDERSERVED COMMUNITIES.—The Secretary may make grants to and enter into contracts with public and nonprofit private entities for the purpose of providing continuing education for nurses serving in medically underserved communities.

(d) LONG-TERM CARE FELLOWSHIPS FOR CERTAIN PARAPROFESSIONALS.—

(1) IN GENERAL.—The Secretary may make grants to and enter into contracts with public and nonprofit private entities that operate accredited programs of education in professional nursing, or State-board approved programs of practical or vocational nursing, for the purpose of providing fellowships to individuals described in paragraph (2) for attendance in such programs.

(2) ELIGIBLE INDIVIDUALS.—The individuals referred to in paragraph (1) are individuals who are employed by nursing facilities or home health agencies as nursing paraprofessionals.

(3) PREFERENCE FOR SCHOOLS WITH RAPID TRANSITION PROGRAMS.—In making awards of grants and contracts under paragraph (1), the Secretary shall give preference to any qualified applicant operating an accredited program of education in professional nursing that provides for the rapid transition to status as a professional nurse from status as a nursing paraprofessional.

(4) PREFERENCE IN AWARD OF FELLOWSHIPS.—The Secretary may make an award of a grant or contract under paragraph (1) only if the applicant involved agrees that, in providing fellowships under the award, the applicant will give preference to individuals described in paragraph (2) who—

(A) are economically disadvantaged individuals, particularly such individuals who are members of a minority

group that is underrepresented among registered nurses; or

(B) are employed by a nursing facility that will assist in paying the costs or expenses described in paragraph (5)(A) with respect to the individuals.

(5) USE OF AWARD.—The Secretary may make an award of a grant or contract under paragraph (1) only if the applicant involved agrees that fellowships provided with the award will pay all or part of the costs of—

(A) the tuition, books, and fees of the program of nursing with respect to which the fellowship is provided; and

(B) reasonable living expenses of the individual during the period for which the fellowship is provided.

(6) DEFINITION.—For purposes of this section:

(A) The term “home health agency” has the meaning given such term in section 1861 of the Social Security Act.

(B) The term “nursing facility” has the meaning given such term in section 1919 of the Social Security Act.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$10,500,000 for each of the fiscal years 1993 and 1994.

ADVANCED NURSE EDUCATION

SEC. 821. [296l] (a) IN GENERAL.—The Secretary may make grants to and enter into contracts with public and nonprofit private collegiate schools of nursing to meet the costs of projects that, in the case of programs described in subsection (b)—

(1) plan, develop, and operate new such programs; or

(2) significantly expand existing such programs.

(b) AUTHORIZED PROGRAMS.—The programs referred to in subsection (a) are programs leading to advanced degrees that prepare nurses to serve as nurse educators or public health nurses, or in other clinical nurse specialties determined by the Secretary to require advanced education.

(c) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$12,000,000 for each of the fiscal years 1993 and 1994.

(2) LIMITATION.—Of the amounts appropriated under paragraph (1), the Secretary may not obligate more than 10 percent for providing grants or contracts under subsection (a) for programs leading to doctoral degrees.

NURSE PRACTITIONER AND NURSE MIDWIFE PROGRAMS

SEC. 822. [296m] (a) IN GENERAL.—The Secretary may make grants to and enter into contracts with public and nonprofit private schools of nursing or other public and nonprofit private entities to meet the costs of projects that, with respect to programs described in subsection (b)—

(1) plan, develop, and operate new such programs; or

(2) maintain or significantly expand existing such programs.

(b) AUTHORIZED PROGRAMS.—

(1) IN GENERAL.—The programs referred to in subsection (a) are educational programs for registered nurses (irrespective of the type of school of nursing in which the nurses received their training) that—

(A) meet guidelines prescribed by the Secretary in accordance with paragraph (2); and

(B) have as their objective the education of nurses who will, upon completion of their studies in such programs, be qualified to effectively provide primary health care, including primary health care in homes and in ambulatory care facilities, long-term care facilities and other health care institutions.

(2) GUIDELINES.—After consultation with appropriate educational organizations and professional nursing and medical organizations, the Secretary shall prescribe guidelines for programs described in paragraph (1). Such guidelines shall, as a minimum, require that such a program—

(A) extend for at least one academic year and consist of—

(i) supervised clinical practice directed toward preparing nurses to deliver primary health care; and

(ii) at least four months (in the aggregate) of classroom instruction that is so directed; and

(B) have an enrollment of not less than six full-time equivalent students.

(c) CERTAIN CONSIDERATIONS IN MAKING AWARDS.—

(1) PREFERENCE.—In making awards of grants and contracts under subsection (a), the Secretary shall give preference to any qualified applicant that, with respect to programs described in subsection (b), agrees to expend the award to plan, develop, and operate new such programs or to significantly expand existing such programs.

(2) SPECIAL CONSIDERATION.—In making awards of grants and contracts under subsection (a), the Secretary shall give special consideration to qualified applicants that agree to expend the award to train individuals as nurse practitioners and nurse midwives who will practice in health professional shortage areas designated under section 332.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$20,000,000 for each of the fiscal years 1993 and 1994.

Subpart II—Nursing Education Opportunities for Individuals From Disadvantaged Backgrounds

SPECIAL PROJECTS

SEC. 827. [296r] (a) The Secretary may make grants to public and nonprofit private schools of nursing and other public or nonprofit private entities, and enter into contracts with any public or private entity, to meet the costs of special projects to increase nursing education opportunities for individuals from disadvantaged backgrounds, as determined in accordance with criteria prescribed by the Secretary—

(1) by identifying, recruiting, and selecting such individuals,

(2) by facilitating the entry of such individuals into schools of nursing,

(3) by providing counseling or other services designed to assist such individuals to complete successfully their nursing education,

(4) by providing, for a period prior to the entry of such individuals into the regular course of education at a school of nursing, preliminary education designed to assist them to complete successfully such regular course of education,

(5) by paying such stipends (including allowances for travel and dependents) as the Secretary may determine for such individuals for any period of nursing education,

(6) by publicizing, especially to licensed vocational or practical nurses, existing sources of financial aid available to persons enrolled in schools of nursing or who are undertaking training necessary to qualify them to enroll in such schools, and

(7) by providing training, information, or advice to the faculty of such schools with respect to encouraging such individuals to complete the programs of nursing education in which the individuals are enrolled.

(b) No grant or contract may be made under this section unless an application therefor has been submitted to and approved by the Secretary. The Secretary may not approve or disapprove such an application except after consultation with the National Advisory Council on Nurse Education. Such an application shall provide for such fiscal control and accounting procedures and reports, and access to the records of the applicant, as the Secretary may require to assure proper disbursement of and accounting for Federal funds paid to the applicant under this section.

(c) For payments under grants and contracts under subsection (a), there are authorized to be appropriated \$3,000,000 for fiscal year 1989, \$4,000,000 for fiscal year 1990, \$5,000,000 for fiscal year 1991, \$5,000,000 for fiscal year 1993, and \$6,000,000 for fiscal year 1994.

PART B—ASSISTANCE TO NURSING STUDENTS

Subpart I—Traineeships

TRAINEESHIPS FOR ADVANCED EDUCATION OF PROFESSIONAL NURSES

SEC. 830. [297] (a) IN GENERAL.—The Secretary may make grants to public and nonprofit private entities to meet the costs of—

(1) traineeships for individuals in advanced-degree programs in order to educate the individuals to serve in and prepare for practice as nurse practitioners, nurse midwives, nurse educators, public health nurses, or in other clinical nursing specialties determined by the Secretary to require advanced education; and

(2) traineeships for participation in certificate nurse midwifery programs that conform to guidelines established by the Secretary under section 822(b).

(b) SPECIAL CONSIDERATION IN MAKING GRANTS.—In making grants for traineeships under subsection (a), the Secretary shall give special consideration to applications for traineeship programs that conform to guidelines established by the Secretary under section 822(b)(2).

(c) PREFERENCE IN PROVISION OF TRAINEESHIPS.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that, in providing traineeships under such subsection, the applicant will give preference to individuals who are residents of health professional shortage areas designated under section 332.

(d) ELIGIBILITY OF INDIVIDUALS IN MASTER'S DEGREE PROGRAMS.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that the applicant will not provide a traineeship under such subsection to an individual enrolled in a masters of nursing program unless the individual has completed basic nursing preparation, as determined by the applicant.

(e) USE OF GRANT.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that traineeships provided with the grant will pay all or part of the costs of—

(A) the tuition, books, and fees of the program of nursing with respect to which the traineeship is provided; and

(B) reasonable living expenses of the individual during the period for which the traineeship is provided.

(f) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$20,000,000 for each of the fiscal years 1993 and 1994.

(2) LIMITATION REGARDING CERTAIN TRAINEESHIPS.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may not obligate more than 10 percent for providing traineeships under subsection (a) for individuals in doctoral degree programs.

NURSE ANESTHETISTS

SEC. 831. [297-1] (a)(1) The Secretary may make grants to public or private nonprofit institutions to cover the costs of traineeships for licensed registered nurses to become nurse anesthetists and to cover the costs of projects to develop and operate programs for the education of nurse anesthetists. In order to be eligible for such a grant, the program of an institution must be accredited by an entity or entities designated by the Secretary of Education and must meet such requirements as the Secretary shall by regulation prescribe.

(2)(A) In making grants under paragraph (1), the Secretary shall give preference to qualified applicants carrying out traineeship programs whose participants gain significant experience in providing health services at rural health facilities.

(B) The Secretary may make a grant under paragraph (1) only if the institution involved agrees that, in providing traineeships under such paragraph, the institution will give preference to individuals who are residents of health professional shortage areas designated under section 332.

(3) The Secretary may make a grant under paragraph (1) only if the applicant involved agrees that traineeships provided with the grant will pay all or part of the costs of—

(A) the tuition, books, and fees of the program of nursing with respect to which the traineeship is provided; and

(B) reasonable living expenses of the individual during the period for which the traineeship is provided.

(b) The Secretary may make grants to public or private non-profit institutions to cover the cost of projects to improve existing programs for the education of nurse anesthetists which are accredited by an entity or entities designated by the Secretary of Education. Such grants shall include grants to such institutions for the purpose of providing financial assistance and support to certified registered nurse anesthetists who are faculty members of accredited programs to enable such nurse anesthetists to obtain advanced education relevant to their teaching functions.

(c) For the purpose of making grants under this section, there is authorized to be appropriated \$1,800,000 for each of the fiscal years 1989 through 1991, \$3,000,000 for fiscal year 1993, and \$4,000,000 for fiscal year 1994. Not more than 20 percent of the amount appropriated under this section for any fiscal year shall be obligated for grants under the second sentence of subsection (b).

Subpart II¹—STUDENT LOANS

LOAN AGREEMENTS

SEC. 835. [297a] (a) The Secretary is authorized to enter into an agreement for the establishment and operation of a student loan fund in accordance with this subpart with any public or nonprofit private school of nursing which is located in a State.

(b) Each agreement entered into under this section shall—

(1) provide for establishment of a student loan fund by the school;

(2) provide for deposit in the fund, except as provided in section 841, of (A) the Federal capital contributions paid from allotments under section 838 to the school by the Secretary, (B) an additional amount from other sources equal to not less than one-ninth of such Federal capital contributions, (C) collections

¹ Section 936(e) of Public Law 94-63 repealed a section of this part that provided for a revolving fund. This former section was section 827. With respect to the revolving fund, such section 936(e) provided as follows: "The nurse training fund created within the Treasury by section 827(d)(1) of the Act shall remain available to the Secretary of Health, Education, and Welfare for the purpose of meeting his responsibilities respecting participations in obligations acquired under section 827 of the Act. The Secretary shall continue to deposit in such fund all amounts received by him as interest payments or repayments of principal on loans under such section 827. If at any time the Secretary determines the moneys in the funds exceed the present and any reasonable prospective further requirements of such fund, such excess may be transferred to the general fund of the Treasury." Such section further provided that "[t]here are authorized to be appropriated without fiscal year limitation such sums as may be necessary to enable the Secretary to make payments under agreements entered into under section 827(b) of the Act before [July 27, 1975]."

of principal and interest on loans made from the fund, (D) collections pursuant to section 836(f), and (E) any other earnings of the fund;

(3) provide that the fund, except as provided in section 841, shall be used only for loans to students of the school in accordance with the agreement and for costs of collection of such loans and interest thereon;

(4) provide that loans may be made from such fund only to students pursuing a full-time or half-time course of study at the school leading to a baccalaureate or associate degree in nursing or an equivalent degree or a diploma in nursing, or to a graduate degree in nursing; and

(5) contain such other provisions as are necessary to protect the financial interests of the United States.

(c)(1) Any standard established by the Secretary by regulation for the collection by schools of nursing of loans made pursuant to loan agreements under this subpart shall provide that the failure of any such school to collect such loans shall be measured in accordance with this subsection. With respect to the student loan fund established pursuant to such agreements, this subsection may not be construed to require such schools to reimburse such loan fund for loans that became uncollectable prior to 1983.

(2) The measurement of a school's failure to collect loans made under this subpart shall be the ratio (stated as a percentage) that the defaulted principal amount outstanding of such school bears to the matured loans of such school.

(3) For purposes of this subsection—

(A) the term "default" means the failure of a borrower of a loan made under this subpart to—

(i) make an installment payment when due; or

(ii) comply with any other term of the promissory note for such loan,

except that a loan made under this subpart shall not be considered to be in default if the loan is discharged in bankruptcy or if the school reasonably concludes from written contacts with the borrower that the borrower intends to repay the loan;

(B) the term "defaulted principal amount outstanding" means the total amount borrowed from the loan fund of a school that has reached the repayment stage (minus any principal amount repaid or cancelled) on loans—

(i) repayable monthly and in default for at least 120 days; and

(ii) repayable less frequently than monthly and in default for at least 180 days;

(C) the term "grace period" means the period of nine months beginning on the date on which the borrower ceases to pursue a full-time or half-time course of study at a school of nursing; and

(D) the term "matured loans" means the total principal amount of all loans made by a school of nursing under this subpart minus the total principal amount of loans made by such school to students who are—

(i) enrolled in a full-time or half-time course of study at such school; or

(ii) in their grace period.

LOAN PROVISIONS

SEC. 836. [297b] (a) The total of the loans for any academic year (or its equivalent, as determined under regulations of the Secretary) made by schools of nursing from loan funds established pursuant to agreements under this subpart may not exceed \$2,500 in the case of any student, except that for the final two academic years of the program involved, such total may not exceed \$4,000. The aggregate of the loans for all years from such funds may not exceed \$13,000 in the case of any student. In the granting of such loans, a school shall give preference to licensed practical nurses, to persons with exceptional financial need, and to persons who enter as first-year students after enactment of this title.

(b) Loans from any such student loan fund by any school shall be made on such terms and conditions as the school may determine; subject, however, to such conditions, limitations, and requirements as the Secretary may prescribe (by regulation or in the agreement with the school) with a view to preventing impairment of the capital of such fund to the maximum extent practicable in the light of the objective of enabling the student to complete his course of study; and except that—

(1) such a loan may be made only to a student who (A) is in need of the amount of the loan to pursue a full-time or half-time course of study at the school leading to a baccalaureate or associate degree in nursing or an equivalent degree, or a diploma in nursing, or a graduate degree in nursing, (B) is capable, in the opinion of the school, of maintaining good standing in such course of study, and (C) with respect to any student enrolling in the school after June 30, 1986, is of financial need (as defined in regulations issued by the Secretary).¹

(2) such a loan shall be repayable in equal or graduated periodic installments (with the right of the borrower to accelerate repayment) over the ten-year period which begins nine months after the student ceases to pursue a full-time or half-time course of study at a school of nursing, excluding from such 10-year period all (A) periods (up to three years) of (i) active duty performed by the borrower as a member of a uniformed service, or (ii) service as a volunteer under the Peace Corps Act, and (B) periods (up to ten years) during which the borrower is pursuing a full-time or half-time course of study at a collegiate school of nursing leading to baccalaureate degree in nursing or an equivalent degree, or to graduate degree in nursing, or is otherwise pursuing advanced professional training in nursing (or training to be a nurse anesthetist);

(3) in the case of a student who received such a loan before the date of enactment of the Nurse Training Amendments of 1979, an amount up to 85 per centum of any such loan made before such date (plus interest thereon) shall be canceled for full-time employment as a professional nurse (including teaching in any of the fields of nurse training and service as an administrator, supervisor, or consultant in any of the fields of

¹ So in original. The period probably should be a semicolon.

nursing) in any public or nonprofit private agency, institution, or organization (including neighborhood health centers), at the rate of 15 per centum of the amount of such loan (plus interest) unpaid on the first day of such service for each of the first, second, and third complete year of such service, and 20 per centum of such amount (plus interest) for each complete fourth and fifth year of such service;

(4) the liability to repay the unpaid balance of such loan and accrued interest thereon shall be canceled upon the death of the borrower, or if the Secretary determines that he has become permanently and totally disabled;

(5) such a loan shall bear interest on the unpaid balance of the loan, computed only for periods during which the loan is repayable, at the rate of 5 percent per annum;

(6) such a loan shall be made without security or endorsement, except that if the borrower is a minor and the note or other evidence of obligation executed by him would not, under the applicable law, create a binding obligation, either security or endorsement may be required;

(7) no note or other evidence of any such loan may be transferred or assigned by the school making the loan except that, if the borrower transfers to another school participating in the program under this subpart, such note or other evidence of a loan may be transferred to such other school.

(c) Where all or any part of a loan, or interest, is canceled under this section, the Secretary shall pay to the school an amount equal to the school's proportionate share of the canceled portion, as determined by the Secretary.

(d) Any loan for any year by a school from a student loan fund established pursuant to an agreement under this subpart shall be made in such installments as may be provided in regulations of the Secretary or such agreement and, upon notice to the Secretary by the school that any recipient of a loan is failing to maintain satisfactory standing, any or all further installments of his loans shall be withheld, as may be appropriate.

(e) An agreement under this subpart with any school shall include provisions designed to make loans from the student loan fund established thereunder reasonably available (to the extent of the available funds in such fund) to all eligible students in the school in need thereof.

(f) Subject to regulations of the Secretary and in accordance with this section, a school shall assess a charge with respect to a loan from the loan fund established pursuant to an agreement under this subpart for failure of the borrower to pay all or any part of an installment when it is due and, in the case of a borrower who is entitled to deferment of the loan under subsection (b)(2) or cancellation of part or all of the loan under subsection (b)(3), for any failure to file timely and satisfactory evidence of such entitlement. No such charge may be made if the payment of such installment or the filing of such evidence is made within 60 days after the date on which such installment or filing is due. The amount of any such charge may not exceed an amount equal to 6 percent of the amount of such installment. The school may elect to add the amount of any such charge to the principal amount of the loan as of the first day

after the day on which such installment or evidence was due, or to make the amount of the charge payable to the school not later than the due date of the next installment after receipt by the borrower of notice of the assessment of the charge.

(g) A school may provide in accordance with regulations of the Secretary, that during the repayment period of a loan from a loan fund established pursuant to an agreement under this subpart payments of principal and interest by the borrower with respect to all the outstanding loans made to him from loan funds so established shall be at a rate equal to not less than \$15 per month.

(h) Notwithstanding the amendment made by section 6(b) of the Nurse Training Act of 1971 to this section—

(A) any person who obtained one or more loans from a loan fund established under this subpart, who before the date of the enactment of the Nurse Training Act of 1971 became eligible for cancellation of all or part of such loans (including accrued interest) under this section (as in effect on the day before such date), and who on such date was not engaged in a service for which loan cancellation was authorized under this section (as so in effect), may at any time elect to receive such cancellation in accordance with this subsection (as so in effect); and

(B) in the case of any person who obtained one or more loans from a loan fund established under this subpart and who on such date was engaged in a service for which cancellation of all or part of such loans (including accrued interest) was authorized under this section (as so in effect), this section (as so in effect) shall continue to apply to such person for purposes of providing such loan cancellation until he terminates such service.

Nothing in this subsection shall be construed to prevent any person from entering into an agreement for loan cancellation under subsection (h)¹ (as amended by section 6(b)(2) of the Nurse Training Act of 1971).

(i) Upon application by a person who received and is under an obligation to repay, any loan made to such person as a nursing student, the Secretary may undertake to repay (without liability to the applicant) all or any part of such loan, and any interest or portion thereof outstanding thereon, upon his determination, pursuant to regulations establishing criteria therefor, that the applicant—

(1) failed to complete the nursing studies with respect to which such loan was made;

(2) is in exceptionally needy circumstances; and

(3) has not resumed, or cannot reasonably be expected to resume, such nursing studies within two years following the date upon which the applicant terminated the studies with respect to which such loan was made.

(j) The Secretary is authorized to attempt to collect any loan which was made under this subpart, which is in default, and which was referred to the Secretary by a school of nursing with which the Secretary has an agreement under this subpart, on behalf of that school under such terms and conditions as the Secretary may pre-

¹ Section 211(a)(1)(A) of Public Law 102-408 (106 Stat. 2078) struck former subsection (h), but did not amend the above reference.

scribe (including reimbursement from the school's student loan fund for expenses the Secretary may reasonably incur in attempting collection), but only if the school has complied with such requirements as the Secretary may specify by regulation with respect to the collection of loans under this subpart. A loan so referred shall be treated as a debt subject to section 5514 of title 5, United States Code. Amounts collected shall be deposited in the school's student loan fund. Whenever the Secretary desires the institution of a civil action regarding any such loan, the Secretary shall refer the matter to the Attorney General for appropriate action.

AUTHORIZATION OF APPROPRIATIONS FOR STUDENT LOAN FUNDS

SEC. 837. [297c] There are authorized to be appropriated for allotments under section 838 to schools of nursing for Federal capital contributions to their student loan funds established under section 835, \$25,000,000 for fiscal year 1976, \$30,000,000 for fiscal year 1977, \$35,000,000 for fiscal year 1978, \$13,500,000 for the fiscal year ending September 30, 1980, \$14,000,000 for the fiscal year ending September 30, 1982, \$16,000,000 for the fiscal year ending September 30, 1983, and \$18,000,000 for the fiscal year ending September 30, 1984. For the fiscal year ending September 30, 1985, and for each of the next two succeeding fiscal years there are authorized to be appropriated such sums as may be necessary to enable students who have received a loan for any academic year ending before October 1, 1984, to continue or complete their education. Of the amount appropriated under the first sentence for the fiscal year ending September 30, 1982, and the two succeeding fiscal years, not less than \$1,000,000 shall be obligated in each such fiscal year for loans from student loan funds established under section 835 to individuals who are qualified to receive such loans and who, on the date they receive the loan, have not been employed on a full-time basis or been enrolled in any educational institution on a full-time basis for at least seven years. A loan to such an individual may not exceed \$500 for any academic year.

ALLOTMENTS AND PAYMENTS OF FEDERAL CAPITAL CONTRIBUTIONS

SEC. 838. [297d] (a)(1) The Secretary shall from time to time set dates by which schools of nursing in a State must file applications for Federal capital contributions.

(2)(A) If the total of the amounts requested for any fiscal year in such applications exceeds the total amount appropriated under section 837 for that fiscal year, the allotment from such total amount to the loan fund of each school of nursing shall be reduced to whichever of the following is the smaller:

(i) The amount requested in its application.

(ii) An amount which bears the same ratio to the total amount appropriated as the number of students estimated by the Secretary to be enrolled on a full-time basis in such school during such fiscal year bears to the estimated total number of students enrolled in all such schools on a full-time basis during such year.

(B) Amounts remaining after allotment under subparagraph (A) shall be reallocated in accordance with clause (ii) of such sub-

paragraph among schools whose applications requested more than the amounts so allotted to their loan funds, but with such adjustments as may be necessary to prevent the total allotted to any such school's loan fund under this paragraph and paragraph (3) from exceeding the total so requested by it.

(3) Funds which, pursuant to section 839(c) or pursuant to a loan agreement under section 835, are returned to the Secretary in any fiscal year, shall be available for allotment until expended. Funds described in the preceding sentence shall be allotted among schools of nursing in such manner as the Secretary determines will best carry out this subpart.

(b) Allotments to a loan fund of a school shall be paid to it from time to time in such installments as the Secretary determines will not result in unnecessary accumulations in the loan fund at such school.

(c) The Federal capital contributions to a loan fund of a school under this subpart shall be paid to it from time to time in such installments as the Secretary determines will not result in unnecessary accumulations in the loan fund at such school.

DISTRIBUTION OF ASSETS FROM LOAN FUNDS

SEC. 839. [297e] (a) After September 30, 1996, and not later than December 31, 1999, there shall be a capital distribution of the balance of the loan fund established under an agreement pursuant to section 835(b) by each school as follows:

(1) The Secretary shall first be paid an amount which bears the same ratio to such balance in such fund at the close of September 30, 1999, as the total amount of the Federal capital contributions to such fund by the Secretary pursuant to section 835(b)(2)(A) bears to the total amount in such fund derived from such Federal capital contributions and from funds deposited therein pursuant to section 835(b)(2)(B).

(2) The remainder of such balance shall be paid to the school.

(b) After December 31, 1999, each school with which the Secretary has made an agreement under this subpart shall pay to the Secretary, not less often than quarterly, the same proportionate share of amounts received by the school after September 30, 1999, in payment of principal or interest on loans made from the loan fund established pursuant to such agreement as was determined for the Secretary under subsection (a).

(c)(1) Within 90 days after the termination of any agreement with a school under section 835 or the termination in any other manner of a school's participation in the loan program under this subpart, such school shall pay to the Secretary from the balance of the loan fund of such school established under section 835, an amount which bears the same ratio to the balance in such fund on the date of such termination as the total amount of the Federal capital contributions to such fund by the Secretary pursuant to section 835(b)(2)(A) bears to the total amount in such fund on such date derived from such Federal capital contributions and from funds deposited in the fund pursuant to section 835(b)(2)(B). The remainder of such balance shall be paid to the school.

(2) A school to which paragraph (1) applies shall pay to the Secretary after the date on which payment is made under such paragraph and not less than quarterly, the same proportionate share of amounts received by the school after the date of termination referred to in paragraph (1) in payment of principal or interest on loans made from the loan fund as was determined for the Secretary under such paragraph.

ADMINISTRATIVE PROVISIONS

SEC. 840. [297g] The Secretary may agree to modifications of agreements made under this subpart, and may compromise, waive, or release any right, title, claim, or demand of the United States arising or acquired under this subpart.

PROCEDURES FOR APPEAL OF TERMINATIONS

SEC. 842. [297i] In any case in which the Secretary intends to terminate an agreement with a school of nursing under this subpart, the Secretary shall provide the school with a written notice specifying such intention and stating that the school may request a formal hearing with respect to such termination. If the school requests such a hearing within 30 days after the receipt of such notice, the Secretary shall provide such school with a hearing conducted by an administrative law judge.

Subpart III—Loan Repayment Program

LOAN REPAYMENT PROGRAM

SEC. 846. [297n] (a) IN GENERAL.—In the case of any individual—

(1) who has received a baccalaureate or associate degree in nursing (or an equivalent degree), a diploma in nursing, or a graduate degree in nursing;

(2) who obtained (A) one or more loans from a loan fund established under subpart II, or (B) any other educational loan for nurse training costs; and

(3) who enters into an agreement with the Secretary to serve as nurse for a period of not less than two years in an Indian Health Service health center, in a Native Hawaiian health center, in a public hospital, in a migrant health center, in a community health center, in a rural health clinic, or in a public or nonprofit private health facility determined by the Secretary to have a critical shortage of nurses;

the Secretary shall make payments in accordance with subsection (b), for and on behalf of that individual, on the principal of and interest on any loan of that individual described in paragraph (2) of this subsection which is outstanding on the date the individual begins the service specified in the agreement described in paragraph (3) of this subsection.

(b) MANNER OF PAYMENTS.—The payments described in subsection (a) shall be made by the Secretary as follows:

(1) Upon completion by the individual for whom the payments are to be made of the first year of the service specified in the agreement entered into with the Secretary under sub-

section (a), the Secretary shall pay 30 percent of the principal of, and the interest on each loan of such individual described in subsection (a)(2) which is outstanding on the date he began such practice.

(2) Upon completion by that individual of the second year of such service, the Secretary shall pay another 30 percent of the principal of, and the interest on each such loan.

(3) Upon completion by that individual of a third year of such service, the Secretary shall pay another 25 percent of the principal of, and the interest on each such loan.

(c) **PAYMENT BY DUE DATE.**—Notwithstanding the requirement of completion of practice specified in subsection (b), the Secretary shall, on or before the due date thereof, pay any loan or loan installment which may fall due within the period of service for which the borrower may receive payments under this subsection, upon the declaration of such borrower, at such times and in such manner as the Secretary may prescribe (and supported by such other evidence as the Secretary may reasonably require), that the borrower is then serving as described by subsection (a)(3), and that the borrower will continue to so serve for the period required (in the absence of this subsection) to entitle the borrower to have made the payments provided by this subsection for such period; except that not more than 85 percent of the principal of any such loan shall be paid pursuant to this subsection.

(d) **BREACH OF AGREEMENT.**—The Secretary may make payments under subsection (a) on behalf of an individual only if the agreement under such subsection provides that section 860(c) is applicable to the individual.

(e) **PREFERENCES REGARDING PARTICIPANTS.**—In entering into agreements under subsection (a), the Secretary shall give preference—

(1) to qualified applicants with the greatest financial need; and

(2) to qualified applicants that, with respect to health facilities described in such subsection, agree to serve in such health facilities located in geographic areas with a shortage of and need for nurses, as determined by the Secretary.

(f) **DEFINITIONS.**—For purposes of this section:

(1) The term “community health center” has the meaning given such term in section 330(a).

(2) The term “migrant health center” has the meaning given such term in section 329(a)(1).

(3) The term “rural health clinic” has the meaning given such term in section 1861(aa)(2) of the Social Security Act.

(g) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of payments under agreements entered into under subsection (a), there are authorized to be appropriated \$5,000,000 for fiscal year 1993, and \$6,000,000 for fiscal year 1994.

PART C—GENERAL

ADVISORY COUNCIL ON NURSE EDUCATION AND PRACTICE; REVIEW COMMITTEE

SEC. 851. [298] (a) There is hereby established a National Advisory Council on Nurse Education and Practice (in this section referred to as the "Council"), consisting of the Secretary or his delegate, who shall be Chairman, and an ex officio member, and twenty-one members appointed by the Secretary without regard to the civil service laws. Three of the appointed members shall be selected from full-time students enrolled in schools of nursing, four of the appointed members shall be selected from the general public, one of the appointed members shall be selected from practicing professional nurses, one of the appointed members shall be selected from among representatives of associate degree schools of nursing, and twelve shall be selected from among leading authorities in the various fields of nursing, higher, and secondary education, and from representatives of hospitals and other institutions and organizations which provide nursing services. The student-members of the Council shall be appointed for terms of one year and shall be eligible for reappointment to the Council.

(b) The Council shall advise the Secretary or his delegate in the preparation of general regulations and with respect to policy matters arising in the administration of this title.

NONINTERFERENCE WITH ADMINISTRATION OF INSTITUTIONS

SEC. 852. [298a] Nothing contained in this title shall be construed as authorizing any department, agency, officer, or employee of the United States to exercise any direction, supervision, or control over, or impose any requirement or condition with respect to the personnel, curriculum, methods of instruction, or administration of any institution.

DEFINITIONS

SEC. 853. [298b] For purposes of this title—

(1) The term "State" means a State, the Commonwealth of Puerto Rico, the District of Columbia, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, or the Trust Territory of the Pacific Islands.

(2) The term "school of nursing" means a collegiate, associate degree, or diploma school of nursing in a State.

(3) The term "collegiate school of nursing" means a department, division, or other administrative unit in a college or university which provides primarily or exclusively a program of education in professional nursing and allied subjects leading to the degree of bachelor of arts, bachelor of science, bachelor of nursing, or to an equivalent degree, or to a graduate degree in nursing, and including advanced training related to such program of education provided by such school, but only if such program, or such unit, college or university is accredited.

(4) The term "associate degree school of nursing" means a department, division, or other administrative unit in a junior college, community college, college, or university which provides primarily

or exclusively a two-year program of education in professional nursing and allied subjects leading to an associate degree in nursing or to an equivalent degree, but only if such program, or such unit, college, or university is accredited.

(5) The term "diploma school of nursing" means a school affiliated with a hospital or university, or an independent school, which provides primary or exclusively a program of education in professional nursing and allied subjects leading to a diploma or to equivalent indicia that such program has been satisfactorily completed, but only if such program, or such affiliated school or such hospital or university or such independent school is accredited.

(6) The term "accredited" when applied to any program of nurse education means a program accredited by a recognized body or bodies, or by a State agency, approved for such purpose by the Secretary of Education and when applied to a hospital, school, college, or university (or a unit thereof) means a hospital, school, college, or university (or a unit thereof) which is accredited by a recognized body or bodies, or by a State agency, approved for such purpose by the Secretary of Education, except that a school of nursing seeking an agreement under subpart II of part B for the establishment of a student loan fund, which is not, at the time of the application under such subpart, eligible for accreditation by such a recognized body or bodies or State agency, shall be deemed accredited for purposes of such subpart if the Secretary of Education finds, after consultation with the appropriate accreditation body or bodies, that there is reasonable assurance that the school will meet the accreditation standards of such body or bodies prior to the beginning of the academic year following the normal graduation date of students who are in their first year of instruction of such school during the fiscal year in which the agreement with such school is made under such subpart; except that the provisions of this clause shall not apply for purposes of section 836. For the purpose of this paragraph, the Secretary of Education shall publish a list of recognized accrediting bodies, and of State agencies, which the Secretary of Education determines to be reliable authority as to the quality of education offered.

(7) The term "nonprofit" as applied to any school, agency, organization, or institution means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(8) The term "secondary school" means a school which provides secondary education, as determined under State law except that it does not include any education provided beyond grade 12.

(9) The terms "construction" and "cost of construction" include (A) the construction of new buildings, and the acquisition, expansion, remodeling, replacement, and alteration of existing buildings, including architects' fees but not including the cost of acquisition of land (except in the case of acquisition of an existing building), off-site improvements, living quarters, or patient-care facilities, and (B) equipping new buildings and existing buildings, whether or not acquired, expanded, remodeled, or altered. For purposes of this paragraph, the term "buildings" includes interim facilities.

(10) The term "interim facilities" means teaching facilities designed to provide teaching space on a short-term (less than ten years) basis while facilities of a more permanent nature are being planned and constructed.

(11) The term "medically underserved community" has the meaning given such term in section 799.

ADVANCE FUNDING

SEC. 854. [298b-1] Any appropriation Act which appropriates funds for any fiscal year for grants, contracts, or other payments under this title may also appropriate for the next fiscal year the funds that are authorized to be appropriated for such payments for such next fiscal year; but no funds may be made available therefrom for obligation for such payments before the fiscal year for which such funds are authorized to be appropriated.

PROHIBITION AGAINST DISCRIMINATION BY SCHOOLS ON THE BASIS OF SEX

SEC. 855. [298b-2] The Secretary may not make a grant, loan guarantee, or interest subsidy payment under this title to, or for the benefit of, any school of nursing unless the application for the grant, loan guarantee, or interest subsidy payment contains assurances satisfactory to the Secretary that the school will not discriminate on the basis of sex in the admission of individuals to its training programs. The Secretary may not enter into a contract under this title with any school unless the school furnishes assurances satisfactory to the Secretary that it will not discriminate on the basis of sex in the admission of individuals to its training programs.

DELEGATION

SEC. 856. [298b-3] The Secretary may delegate the authority to administer any program authorized by this title to the administrator of a central or regional office or offices in the Department of Health and Human Services, except that the authority—

(1) to review, and prepare comments on the merit of, any application for a grant or contract under any program authorized by this title for purposes of presenting such application to the Advisory Council on Nurses Education, or

(2) to make such a grant or enter into such a contract, shall not be further delegated to any administrator of, or officer in, any regional office or offices in the Department.

TECHNICAL ASSISTANCE

SEC. 857. [298b-4] Funds appropriated under this title may be used by the Secretary to provide technical assistance in relation to any of the authorities under this title.

RECOVERY FOR CONSTRUCTION ASSISTANCE

SEC. 858. [298b-5] (a) If at any time within 20 years (or within such shorter period as the Secretary may prescribe by regulation for an interim facility) after the completion of construction of a fa-

cility with respect to which funds have been paid under subpart I of part A (as such subpart was in effect on September 30, 1985)—

(1) the owner of the facility ceases to be a public or non-profit school,

(2) the facility ceases to be used for the training purposes for which it was constructed, or

(3) the facility is used for sectarian instruction or as a place for religious worship,

the United States shall be entitled to recover from the owner of the facility the base amount prescribed by subsection (c)(1) plus the interest (if any) prescribed by subsection (c)(2).

(b) The owner of a facility which ceases to be a public or non-profit school as described in paragraph (1) of subsection (a), or the owner of a facility the use of which changes as described in paragraph (2) or (3) of such subsection shall provide the Secretary written notice of such cessation or change of use within 10 days after the date on which such cessation or change of use occurs or within 30 days after the date of enactment of the Health Professions Training Assistance Act of 1985, whichever is later.

(c)(1) The base amount that the United States is entitled to recover under subsection (a) is the amount bearing the same ratio to the then value (as determined by the agreement of the parties or in an action brought in the district court of the United States for the district in which the facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction.

(2)(A) The interest that the United States is entitled to recover under subsection (a) is the interest for the period (if any) described in subparagraph (B) at a rate (determined by the Secretary) based on the average of the bond equivalent rates of 91-day Treasury bills auctioned during such period.

(B) The period referred to in subparagraph (A) is the period beginning—

(i) if notice is provided as prescribed by subsection (b), 191 days after the date on which the owner of the facility ceases to be a public or nonprofit school as described in paragraph (1) of subsection (a), or 191 days after the date on which the use of the facility changes as described in paragraph (2) or (3) of such subsection, or

(ii) if notice is not provided as prescribed by subsection (b), 11 days after the date on which such cessation or change of use occurs,

and ending on the date the amount the United States is entitled to recover is collected.

(d) The Secretary may waive the recovery rights of the United States under subsection (a)(2) with respect to a facility (under such conditions as the Secretary may establish by regulation) if the Secretary determines that there is good cause for waiving such rights.

(e) The right of recovery of the United States under subsection (a) shall not, prior to judgment, constitute a lien on any facility.

EVALUATIONS

SEC. 859. [298b-6] (a) The Secretary shall, directly or through contracts with public and private entities, provide for evaluations

of projects carried out pursuant to this title and for the dissemination of information developed as result¹ of such projects. Such evaluations shall include an evaluation of the effectiveness of such projects in increasing the recruitment and retention of nurses.

(b) The Secretary shall, not later than January 10, 1994, and every 2 years thereafter, submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report summarizing evaluations carried out pursuant to subsection (a) during the preceding two fiscal years.

(c) Of the amounts appropriated each fiscal year to carry out this title, the Secretary shall make available one percent to carry out this section.

CERTAIN GENERALLY APPLICABLE PROVISIONS

SEC. 860. [298b-7] (a) APPLICATION FOR GRANTS, COOPERATIVE AGREEMENTS, OR CONTRACTS.—The Secretary may make an award of a grant, cooperative agreement, or contract under this title only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the program authorizing the award.

(b) DURATION OF ASSISTANCE.—

(1) IN GENERAL.—Subject to paragraph (2), in the case of an award to an entity of a grant, cooperative agreement, or contract under this title, the period during which payments are made to the entity under the award may not exceed 5 years. The provision of payments under the award shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments. This paragraph may not be construed as limiting the number of awards under the program involved that may be made to the entity.

(2) LIMITATION.—In the case of an award to an entity of a grant, cooperative agreement, or contract under this title, paragraph (1) shall apply only to the extent not inconsistent with any other provision of this title that relates to the period during which payments may be made under the award.

(c) BREACH OF AGREEMENTS FOR OBLIGATED SERVICE.—

(1) IN GENERAL.—In the case of any program under this title under which an individual makes an agreement to provide health services for a period of time in accordance with such program in consideration of receiving an award of Federal funds regarding education as a nurse (including an award for the repayment of loans), the following applies if the agreement provides that this subsection is applicable:

(A) In the case of a program under this title that makes an award of Federal funds for attending an accredited program of nursing (in this subsection referred to as²

¹ So in original. Probably should be "as a result".

² So in original. See section 209 of Public Law 102-408 (106 Stat. 2075). Probably should be "as a 'nursing program'".

"nursing program"), the individual is liable to the Federal Government for the amount of such award (including amounts provided for expenses related to such attendance), and for interest on such amount at the maximum legal prevailing rate, if the individual—

(i) fails to maintain an acceptable level of academic standing in the nursing program (as indicated by the program in accordance with requirements established by the Secretary);

(ii) is dismissed from the nursing program for disciplinary reasons; or

(iii) voluntarily terminates the nursing program.

(B) The individual is liable to the Federal Government for the amount of such award (including amounts provided for expenses related to such attendance), and for interest on such amount at the maximum legal prevailing rate, if the individual fails to provide health services in accordance with the program under this title for the period of time applicable under the program.

(2) **WAIVER OR SUSPENSION OF LIABILITY.**—In the case of an individual or health facility making an agreement for purposes of paragraph (1), the Secretary shall provide for the waiver or suspension of liability under such paragraph if compliance by the individual or the health facility, as the case may be, with the agreements involved is impossible, or would involve extreme hardship to the individual or facility, and if enforcement of the agreements with respect to the individual or facility would be unconscionable.

(3) **DATE CERTAIN FOR RECOVERY.**—Subject to paragraph (2), any amount that the Federal Government is entitled to recover under paragraph (1) shall be paid to the United States not later than the expiration of the three-year period beginning on the date the United States becomes so entitled.

(4) **AVAILABILITY.**—Amounts recovered under paragraph (1) with respect to a program under this title shall be available for the purposes of such program, and shall remain available for such purposes until expended.

(d) **PEER REVIEW REGARDING CERTAIN PROGRAMS.**—Each application for a grant or contract under any of sections 821, 822, 827, 830, and 831¹ shall be submitted to a peer review group for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval. Each peer review group under this subsection shall be composed principally of individuals who are not officers or employees of the Federal Government. This subsection shall be carried out by the Secretary acting through the Administrator of the Health Resources and Services Administration.

¹Section 2014(g) of Public Law 103-43 (107 Stat. 217) provides that section 860(d) is amended by striking "821, 822, 830, and 831" and inserting "821, 822, and 827". Although the intent of the Congress is clear, the amendment cannot be executed because, as a result of section 313(a)(10) of Public Law 102-531 (106 Stat. 3507), the language to be struck by the amendment does not appear in section 860(d). (This latter Public Law added "827," after "822," thus modifying section 860(d) as first enacted by section 209 of Public Law 102-408 (106 Stat. 2075).)

(e) PREFERENCES AND REQUIRED INFORMATION IN CERTAIN PROGRAMS.—

(1) PREFERENCES IN MAKING AWARDS.—

(A) Subject to subparagraph (B), in awarding grants or contracts under any of sections 821, 822, 830, and 831, the Secretary shall give preference to any qualified applicant that—

(i) has a high rate for placing graduates in practice settings having the principal focus of serving residents of medically underserved communities; or

(ii) during the 2-year period preceding the fiscal year for which such an award is sought, has achieved a significant increase in the rate of placing graduates in such settings.

(B) For purposes of subparagraph (A), the Secretary may not give an applicant preference if the proposal of the applicant is ranked at or below the 20th percentile of proposals that have been recommended for approval by peer review groups under subsection (d).

(2) REQUIRED SUBMISSION OF INFORMATION.—The Secretary may make an award of a grant or contract under any of sections 821, 822, 830, and 831 only if the applicant for the award submits to the Secretary (through the application for the award) the following information regarding the programs of the applicant:

(A) A description of rotations or preceptorships for students that have the principal focus of providing health care to medically underserved communities.

(B) The number of faculty on admissions committees who have a clinical practice in community-based ambulatory settings in medically underserved or rural communities.

(C) With respect to individuals who are from disadvantaged backgrounds or from medically underserved communities, the number of such individuals who are recruited for academic programs of the applicant, the number of such individuals who are admitted to such programs, and the number of such individuals who graduate from such programs.

(D) If applicable to the applicant, the number of recent graduates who have chosen careers in primary health care.

(E) The number of recent graduates whose practices are serving medically underserved communities.

(F) A description of whether and to what extent the applicant is able to operate without Federal assistance under this title.

(3) DEFINITION.—For purposes of this subsection, the term “graduate” means, unless otherwise specified, an individual who has successfully completed all training requirements necessary for full certification in the health profession selected by the individual.

TITLE IX—AGENCY FOR HEALTH CARE POLICY AND RESEARCH

PART A—ESTABLISHMENT AND GENERAL DUTIES

SEC. 901. [299] ESTABLISHMENT.

(a) IN GENERAL.—There is established within the Service an agency to be known as the Agency for Health Care Policy and Research.

(b) PURPOSE.—The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice (including the prevention of diseases and other health conditions) and in the organization, financing, and delivery of health care services.

(c) APPOINTMENT OF ADMINISTRATOR.—There shall be at the head of the Agency an official to be known as the Administrator for Health Care Policy and Research. The Administrator shall be appointed by the Secretary. The Secretary, acting through the Administrator, shall carry out the authorities and duties established in this title.

SEC. 902. [299a] GENERAL AUTHORITIES AND DUTIES.

(a) IN GENERAL.—In carrying out section 901(b), the Administrator shall conduct and support research, demonstration projects, evaluations, training, guideline development, and the dissemination of information, on health care services and on systems for the delivery of such services, including activities with respect to—

- (1) the effectiveness, efficiency, and quality of health care services;
- (2) subject to subsection (d), the outcomes of health care services and procedures;
- (3) clinical practice, including primary care and practice-oriented research;
- (4) health care technologies, facilities, and equipment;
- (5) health care costs, productivity, and market forces;
- (6) health promotion and disease prevention;
- (7) health statistics and epidemiology; and
- (8) medical liability.

(b) REQUIREMENTS WITH RESPECT TO RURAL AREAS AND UNDERSERVED POPULATIONS.—In carrying out subsection (a), the Administrator shall undertake and support research, demonstration projects, and evaluations with respect to—

- (1) the delivery of health care services in rural areas (including frontier areas); and
- (2) the health of low-income groups, minority groups, and the elderly.

(c) **HEALTH SERVICES TRAINING GRANTS.**—The Administrator may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate.

(d) **MULTIDISCIPLINARY CENTERS.**—The Administrator may provide financial assistance to public or nonprofit private entities for meeting the costs of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services research, demonstration projects, evaluations, training, policy analysis, and demonstrations respecting the matters referred to in subsection (a).

(e) **RELATION TO CERTAIN AUTHORITIES REGARDING SOCIAL SECURITY.**—Activities authorized in this section may include, and shall be appropriately coordinated with, experiments, demonstration projects, and other related activities authorized by the Social Security Act and the Social Security Amendments of 1967. Activities under subsection (a)(2) of this section that affect the programs under titles XVIII and XIX of the Social Security Act shall be carried out consistent with section 1142¹ of such Act.

SEC. 903. [299a-1] DISSEMINATION.

(a) **IN GENERAL.**—The Administrator shall—

(1) promptly publish, make available, and otherwise disseminate, in a form understandable and on as broad a basis as practicable so as to maximize its use, the results of research, demonstration projects, and evaluations conducted or supported under this title and the guidelines, standards, and review criteria developed under this title;

(2) promptly make available to the public data developed in such research, demonstration projects, and evaluations;

(3) provide indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on research, demonstration projects, and evaluations with respect to health care to public and private entities and individuals engaged in the improvement of health care delivery and the general public, and undertake programs to develop new or improved methods for making such information available; and

(4) as appropriate, provide technical assistance to State and local government and health agencies and conduct liaison activities to such agencies to foster dissemination.

(b) **PROHIBITION AGAINST RESTRICTIONS.**—Except as provided in subsection (c), the Administrator may not restrict the publication or dissemination of data from, or the results of, projects conducted or supported under this title.

(c) **LIMITATION ON USE OF CERTAIN INFORMATION.**—No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regu-

¹ The text of section 1142 of the Social Security Act is provided in this compilation under the heading "Certain Provisions Relating to Outcomes of Health Care".

lations of the Secretary) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(d) CERTAIN INTERAGENCY AGREEMENT.—The Administrator and the Director of the National Library of Medicine shall enter into an agreement providing for the implementation of subsection (a)(3).

(e) REQUIRED INTERAGENCY AGREEMENT.—The Administrator and the Director of the National Library of Medicine shall enter into an agreement providing for the implementation of section 478A.

SEC. 904. [299a-2] HEALTH CARE TECHNOLOGY AND TECHNOLOGY ASSESSMENT.

(a) IN GENERAL.—In carrying out section 901(b), the Administrator shall promote the development and application of appropriate health care technology assessments—

(1) by identifying needs in, and establishing priorities for, the assessment of specific health care technologies;

(2) by developing and evaluating criteria and methodologies for health care technology assessment;

(3) by conducting and supporting research on the development and diffusion of health care technology;

(4) by conducting and supporting research on assessment methodologies;

(5) by promoting education, training, and technical assistance in the use of health care technology assessment methodologies and results; and

(6) by conducting assessments and reassessments of existing and new health care technologies.

(b) SPECIFIC ASSESSMENTS.—

(1) IN GENERAL.—In carrying out section 901(b), the Administrator shall conduct and support specific assessments of health care technologies.

(2) CONSIDERATION OF CERTAIN FACTORS.—In carrying out paragraph (1), the Administrator shall consider the safety, efficacy, and effectiveness, and, as appropriate, the legal, social, and ethical implications, and appropriate uses of such technologies, including consideration of geographic factors. In carrying out such paragraph, the Administrator shall also consider the cost effectiveness of such technologies where cost information is available and reliable.

(c) AGENDA AND PRIORITIES.—

(1) ESTABLISHMENT OF PRIORITIES.—In accordance with paragraph (2), the Administrator, in consultation with the Advisory Council established under section 921, shall establish an annual list of technology assessments under consideration by the Agency, including those assessments performed at the request of the Health Care Financing Administration and the Department of Defense and those assessments performed under subsections (d) and (f).

(2) PUBLIC NOTICE.—The Administrator, in consultation with the Advisory Council, shall publish the list established in paragraph (1) annually in the Federal Register.

(d)¹ CONDUCT OF ASSESSMENTS.—

(1) RECOMMENDATIONS WITH RESPECT TO HEALTH CARE TECHNOLOGY.—The Administrator shall make recommendations to the Secretary with respect to whether specific health care technologies should be reimbursable under federally financed health programs, including recommendations with respect to any conditions and requirements under which any such reimbursements should be made.

(2) CONSIDERATIONS OF CERTAIN FACTORS.—In making recommendations respecting health care technologies, the Administrator shall consider the safety, efficacy, and effectiveness, and, as appropriate, the appropriate uses of such technologies. The Administrator shall also consider the cost effectiveness of such technologies where cost information is available and reliable.

(3) ADDITIONAL ASSESSMENTS.—The Administrator may conduct technology assessments in addition to those assessments performed at the request of the Administrator of the Health Care Financing Administration or of the Secretary of Defense.

(4) CRITERIA.—The Administrator shall develop criteria for determining the priority of assessments performed under this subsection. Such criteria shall include—

(A) the prevalence of the health condition for which the technology aims to prevent, diagnose, treat and clinically manage;

(B) variations in current practice;

(C) the economic burden posed by the prevention, diagnosis, treatment, and clinical management of the health condition, including the impact on publicly-funded programs;

(D) aggregate cost of the use of technology;

(E) the morbidity and mortality associated with the health condition; and

(F) the potential of an assessment to improve health outcomes or affect costs associated with the prevention, diagnosis, or treatment of the condition.

(5) CONSULTATIONS.—In carrying out this subsection, the Administrator shall cooperate and consult with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency.

(e)¹ DESCRIPTION OF PROCESS.—Not later than January 1, 1994, the Administrator shall develop and publish a description of the methodology used to establish priorities for technology assessment and the process used to conduct its technology assessments under this section.

(f)¹ PROGRAM OF INNOVATIVE ASSESSMENTS.—

¹ Section 4(a)(4) of Public Law 102-410 (106 Stat. 2095) provided that section 904 is amended “in subsection (d), to read as follows:”, and then stated the text of subsections (d), (e), and (f) as shown above.

(1) **IN GENERAL.**—The Administrator may make grants to, or enter cooperative agreements or contracts with, entities described in paragraph (2) for the establishment of collaborative arrangements for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded health care technologies, and for related activities. Such assessments may include controlled clinical trials, large simple trials, and other methodologies that can be conducted in partnership between the public and private sectors or among multiple government agencies.

(2) **ELIGIBLE ENTITIES.**—The entities referred to in paragraph (1) are entities determined to be appropriate by the Administrator, which entities may include academic medical centers, research institutions, nonprofit professional organizations, public or private third party payers, other governmental agencies, and consortia of appropriate research entities established for the purpose of conducting technology assessments.

(3) **USE OF AWARD.**—A grant, cooperative agreement, or contract under paragraph (1) may be expended for data collection, data analysis, protocol development, report development, dissemination and evaluation, and other activities determined to be appropriate by the Administrator. Such funds shall not be used for direct services.

(4) **APPLICATION FOR AWARD.**—To be eligible to receive a grant, cooperative agreement, or contract under paragraph (1), an entity shall prepare and submit to the Administrator an application, at such time, in such form, and containing such information as the Administrator may require.

(5) **INTERAGENCY MEMORANDA OF UNDERSTANDING.**—In carrying out paragraph (1), the Administrator may enter into memoranda of understanding with the heads of other Federal agencies.

PART B—FORUM FOR QUALITY AND EFFECTIVENESS IN HEALTH CARE

SEC. 911. [299b] ESTABLISHMENT OF OFFICE.

There is established within the Agency an office to be known as the Office of the Forum for Quality and Effectiveness in Health Care. The office shall be headed by a director, who shall be appointed by the Administrator. The Administrator shall carry out this part acting through the Director.

SEC. 912. [299b-1] DUTIES.

(a) **ESTABLISHMENT OF FORUM PROGRAM.**—The Administrator shall establish a program to be known as the Forum for Quality and Effectiveness in Health Care. For the purpose of promoting the quality, appropriateness, and effectiveness of health care, the Administrator, using the process set forth in section 913, shall arrange for the development and periodic review and updating of—

(1) clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically; and

(2) standards of quality, performance measures, and medical review criteria through which health care providers and other appropriate entities may assess or review the provision of health care and assure the quality of such care.

(b) CERTAIN REQUIREMENTS.—Guidelines, standards, performance measures, and review criteria under subsection (a) shall—

(1) be based on the best available research and professional judgment regarding the effectiveness and appropriateness of health care services and procedures;

(2) be presented in formats appropriate for use by physicians, health care practitioners, providers, medical educators, and medical review organizations and in formats appropriate for use by consumers of health care;

(3) include treatment-specific or condition-specific practice guidelines for clinical treatments and conditions in forms appropriate for use in clinical practice, for use in educational programs, and for use in reviewing quality and appropriateness of medical care; and¹

(4) include information on risks and benefits of alternative strategies for prevention, diagnosis, treatment, and management of a given disease, disorder, or other health condition; and

(5) include information on the costs of alternative strategies for the prevention, diagnosis, treatment, and management of a given disease, disorder, or other health condition, where cost information is available and reliable.

(c) AUTHORITY FOR CONTRACTS.—In carrying out this part, the Administrator may enter into contracts with public or nonprofit private entities.

(d) DATE CERTAIN FOR INITIAL GUIDELINES AND STANDARDS.—The Administrator, by not later than January 1, 1991, shall assure the development of an initial set of guidelines, standards, performance measures, and review criteria under subsection (a) that includes not less than 3 clinical treatments or conditions described in section 1142(a)(3)² of the Social Security Act.

(e) RELATIONSHIP WITH MEDICARE PROGRAM.—To assure an appropriate reflection of the needs and priorities of the program under title XVIII of the Social Security Act, activities under this part that affect such program shall be conducted consistent with section 1142¹ of such Act.

(f) DEVELOPMENT OF CERTAIN GUIDELINES AND STANDARDS.—Not later than January 1, 1996, the Administrator shall ensure that a set of guidelines, standards, performance measures, and review criteria, are developed under subsection (a)(1) that address the prevention of not fewer than three conditions that account for significant national health expenditures. In carrying out this subsection the Administrator shall consult with the United States Preventive Services Task Force and other recognized experts in the field of disease prevention.

¹ So in law. See section 5(a)(1)(C) of Public Law 102-410 (106 Stat. 2097). The word "and" should probably be deleted.

² See footnote 1 on page 580.

SEC. 913. [299b-2] PROCESS FOR DEVELOPMENT OF GUIDELINES AND STANDARDS.

(a) **DEVELOPMENT THROUGH CONTRACTS AND PANELS.**—The Administrator shall—

(1) enter into contracts with public and nonprofit private entities for the purpose of developing and periodically reviewing and updating the guidelines, standards, performance measures, and review criteria described in section 912(a); and

(2) convene panels of appropriately qualified experts (including practicing physicians with appropriate expertise) and health care consumers for the purpose of—

(A) developing and periodically reviewing and updating the guidelines, standards, performance measures, and review criteria described in section 912(a); and

(B) reviewing the guidelines, standards, performance measures, and review criteria developed under contracts under paragraph (1).

(b) **AUTHORITY FOR ADDITIONAL PANELS.**—The Administrator may convene panels of appropriately qualified experts (including practicing physicians with appropriate expertise) and health care consumers for the purpose of—

(1) developing the standards and criteria described in section 914(b); and

(2) providing advice to the Administrator and the Director with respect to any other activities carried out under this part or under section 902(a)(2).

(c) The Administrator shall select the chairpersons and the members of the panels convened as well as other participants in the guideline process under this section.¹ **SELECTION OF PANEL MEMBERS.**—In selecting individuals to serve on panels convened under this section, the Administrator shall consult with a broad range of interested individuals and organizations, including organizations representing physicians in the general practice of medicine and organizations representing physicians in specialties and subspecialties pertinent to the purposes of the panel involved. The Administrator shall seek to appoint physicians reflecting a variety of practice settings. In making such selections, the Administrator shall ensure that a balance is maintained between individuals selected from academic settings and individuals selected without full-time academic appointments. At least two other members of such panels shall be individuals who do not derive their primary source of revenue directly from the performance of procedures discussed in the guideline. The Administrator shall ensure that at least one participant in the guideline process shall have expertise in epidemiology as well as familiarity with the clinical condition or treatment in question. The Administrator shall also ensure that at least one participant in the guideline process shall have expertise in health services research or health economics as well as familiarity with the clinical condition or treatment in question.

SEC. 914. [299b-3] ADDITIONAL REQUIREMENTS.

(a) **PROGRAM AGENDA.**—

¹ So in law. Section 5(f)(1)(A)(i) of Public Law 102-410 (106 Stat. 2099) amended section 913(c) "by inserting after the subsection designation" the above sentence.

(1) IN GENERAL.—The Administrator shall provide for an agenda for the development of the guidelines, standards, performance measures, and review criteria described in section 912(a), including—

(A) with respect to the guidelines, identifying specific diseases, disorders, and other health conditions for which the guidelines are to be developed and those that are to be given priority in the development of the guidelines; and

(B) with respect to the standards, performance measures, and review criteria, identifying specific aspects of health care for which the standards, performance measures, and review criteria are to be developed and those that are to be given priority in the development of the standards, performance measures, and review criteria.

(2) CONSIDERATION OF CERTAIN FACTORS IN ESTABLISHING PRIORITIES.—

(A) Factors considered by the Administrator in establishing priorities for purposes of paragraph (1) shall include consideration of the extent to which the guidelines, standards, performance measures, and review criteria involved can be expected—

(i) to improve methods for disease prevention;

(ii) to improve methods of diagnosis, treatment, and clinical management for the benefit of a significant number of individuals;

(iii) to reduce clinically significant variations among physicians in the particular services and procedures utilized in making diagnoses and providing treatments; and

(iv) to reduce clinically significant variations in the outcomes of health care services and procedures.

(B) In providing for the agenda required in paragraph (1), including the priorities, the Administrator shall consult with the Administrator of the Health Care Financing Administration and otherwise act consistent with section 1142(b)(3)¹ of the Social Security Act.

(C) The Administrator shall develop and publish a methodology for establishing priorities for guideline topics. Such methodology may include the considerations described in section 904(d)(2) or 914(a)(2), and other considerations determined by the Administrator to be appropriate. Using such methodology, the Administrator shall establish and publish annually in the Federal Register a list of guideline topics under consideration.

(b) STANDARDS AND CRITERIA.—

(1) PROCESS FOR DEVELOPMENT, REVIEW, AND UPDATING.—The Administrator shall establish standards and criteria to be utilized by the recipients of contracts under section 913, and by the expert panels convened under such section, with respect to the development and periodic review and updating of the guidelines, standards, performance measures, and review criteria described in section 912(a).

¹ See footnote 1 on page 580.

(2) AWARD OF CONTRACTS.—The Administrator shall establish standards and criteria to be utilized for the purpose of ensuring that contracts entered into for the development or periodic review or updating of the guidelines, standards, performance measures, and review criteria described in section 912(a) will be entered into only with appropriately qualified entities.

(3) CERTAIN REQUIREMENTS FOR STANDARDS AND CRITERIA.—The Administrator shall ensure that the standards and criteria established under paragraphs (1) and (2) specify that—

(A) appropriate consultations with interested individuals and organizations are to be conducted in the development of the guidelines, standards, performance measures, and review criteria described in section 912(a); and

(B) such development may be accomplished through the adoption, with or without modification, of guidelines, standards, performance measures, and review criteria that—

(i) meet the requirements of this part; and

(ii) are developed by entities independently of the program established in this part.

(4) IMPROVEMENTS OF STANDARDS AND CRITERIA.—The Administrator shall conduct and support research with respect to improving the standards and criteria developed under this subsection.

(c) DISSEMINATION.—The Administrator shall promote and support the dissemination of the guidelines, standards, performance measures, and review criteria described in section 912(a). Such dissemination shall be carried out through organizations representing health care providers, organizations representing health care consumers, peer review organizations, accrediting bodies, and other appropriate entities.

(d) PILOT TESTING.—The Administrator may conduct or support pilot testing of the guidelines, standards, performance measures, and review criteria developed under section 912(a). Any such pilot testing may be conducted prior to, or concurrently with, their dissemination under subsection (c).

(e) EVALUATIONS.—The Administrator shall conduct and support evaluations of the extent to which the guidelines, standards, performance standards, and review criteria developed under section 912 have had an effect on the clinical practice of medicine. Evaluations shall be developed prior to the completion and release of the guideline, so that baseline data concerning practice patterns and health care costs may be obtained as part of the evaluation.

(f) RECOMMENDATIONS TO ADMINISTRATOR.—The Director shall make recommendations to the Administrator on activities that should be carried out under section 902(a)(2) and under section 1142¹ of the Social Security Act, including recommendations of particular research projects that should be carried out with respect to—

(1) evaluating the outcomes of health care services and procedures;

¹ See footnote 1 on page 580.

(2) developing the standards and criteria required in subsection (b); and

(3) promoting the utilization of the guidelines, standards, performance standards, and review criteria developed under section 912(a).

PART C—GENERAL PROVISIONS

SEC. 921. [299c] ADVISORY COUNCIL FOR HEALTH CARE POLICY, RESEARCH, AND EVALUATION.

(a) ESTABLISHMENT.—There is established an advisory council to be known as the National Advisory Council for Health Care Policy, Research, and Evaluation.

(b) DUTIES.—

(1) IN GENERAL.—The Council shall advise the Secretary and the Administrator with respect to activities to carry out the purpose of the Agency under section 901(b).

(2) CERTAIN RECOMMENDATIONS.—Activities of the Council under paragraph (1) shall include making recommendations to the Administrator regarding priorities for a national agenda and strategy for—

(A) the conduct of research, demonstration projects, and evaluations with respect to health care, including clinical practice and primary care;

(B) the development and application of appropriate health care technology assessments;

(C) the development and periodic review and updating of guidelines for clinical practice, standards of quality, performance measures, and medical review criteria with respect to health care; and

(D) the conduct of research on outcomes of health care services and procedures.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Council shall, in accordance with this subsection, be composed of appointed members and ex officio members. All members of the Council shall be voting members, other than officials designated under paragraph (3)(B) as ex officio members of the Council.

(2) APPOINTED MEMBERS.—The Secretary shall appoint to the Council 17 appropriately qualified representatives of the public who are not officers or employees of the United States. The Secretary shall ensure that the appointed members of the Council, as a group, are representative of professions and entities concerned with, or affected by, activities under this title and under section 1142¹ of the Social Security Act. Of such members—

(A) 8 shall be individuals distinguished in the conduct of research, demonstration projects, and evaluations with respect to health care;

(B) 3 shall be individuals distinguished in the practice of medicine;

(C) 2 shall be individuals distinguished in the health professions;

¹ See footnote 1 on page 580.

(D) 2 shall be individuals distinguished in the fields of business, law, ethics, economics, and public policy; and

(E) 2 shall be individuals representing the interests of consumers of health care.

(3) EX OFFICIO MEMBERS.—The Secretary shall designate as ex officio members of the Council—

(A) the Director of the National Institutes of Health, the Director of the Centers for Disease Control, the Administrator of the Health Care Financing Administration, the Assistant Secretary of Defense (Health Affairs), the Chief Medical Officer of the Department of Veterans Affairs; and

(B) such other Federal officials as the Secretary may consider appropriate.

(d) TERMS.—

(1) IN GENERAL.—Except as provided in paragraph (2), members of the Council appointed under subsection (c)(2) shall serve for a term of 3 years.

(2) STAGGERED ROTATION.—Of the members first appointed to the Council under subsection (c)(2), the Secretary shall appoint 6 members to serve for a term of 3 years, 6 members to serve for a term of 2 years, and 5 members to serve for a term of 1 year.

(3) SERVICE BEYOND TERM.—A member of the Council appointed under subsection (c)(2) may continue to serve after the expiration of the term of the member until a successor is appointed.

(e) VACANCIES.—If a member of the Council appointed under subsection (c)(2) does not serve the full term applicable under subsection (d), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(f) CHAIR.—The Administrator shall, from among the members of the Council appointed under subsection (c)(2), designate an individual to serve as the chair of the Council.

(g) MEETINGS.—The Council shall meet not less than once during each discrete 4-month period and shall otherwise meet at the call of the Administrator or the chair.

(h) COMPENSATION AND REIMBURSEMENT OF EXPENSES.—

(1) APPOINTED MEMBERS.—Members of the Council appointed under subsection (c)(2) shall receive compensation for each day (including traveltime) engaged in carrying out the duties of the Council. Such compensation may not be in an amount in excess of the maximum rate of basic pay payable for GS-18 of the General Schedule.

(2) EX OFFICIO MEMBERS.—Officials designated under subsection (c)(3) as ex officio members of the Council may not receive compensation for service on the Council in addition to the compensation otherwise received for duties carried out as officers of the United States.

(i) STAFF.—The Administrator shall provide to the Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

(j) DURATION.—Notwithstanding section 14(a) of the Federal Advisory Committee Act, the Council shall continue in existence until otherwise provided by law.

SEC. 922. [299c-1] PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS.

(a) REQUIREMENT OF REVIEW.—

(1) IN GENERAL.—Appropriate technical and scientific peer review shall be conducted with respect to each application for a grant, cooperative agreement, or contract under this title.

(2) REPORTS TO ADMINISTRATOR.—Each peer review group to which an application is submitted pursuant to paragraph (1) shall report its finding and recommendations respecting the application to the Administrator in such form and in such manner as the Administrator shall require.

(b) APPROVAL AS PRECONDITION OF AWARDS.—The Administrator may not approve an application described in subsection (a)(1) unless the application is recommended for approval by a peer review group established under subsection (c).

(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

(1) IN GENERAL.—The Administrator shall establish such technical and scientific peer review groups as may be necessary to carry out this section. Such groups shall be established without regard to the provisions of title 5, United States Code, that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

(2) MEMBERSHIP.—The members of any peer review group established under this section shall be appointed from among individuals who by virtue of their training or experience are eminently qualified to carry out the duties of such peer review group. Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group. Such officers and employees may not receive compensation for service on such groups in addition to the compensation otherwise received for duties carried out as such officers and employees.

(3) DURATION.—Notwithstanding section 14(a) of the Federal Advisory Committee Act, peer review groups established under this section shall continue in existence until otherwise provided by law.

(d) CATEGORIES OF REVIEW.—

(1) IN GENERAL.—With respect to technical and scientific peer review under this section, there shall be two categories of peer review groups as follows:

(A) One category of such groups shall, subject to subparagraph (B), review applications with respect to research, demonstration projects, or evaluations.

(B) The other category of such groups shall review applications with respect to dissemination activities or the development of research agendas (including conferences, workshops, and meetings). If the purpose of a proposal presented in an application is a matter described in the preceding sentence, the application shall be reviewed by the

groups referred to in such sentence, notwithstanding that the proposal involves research, demonstration projects, or evaluations.

(2) **AUTHORITY FOR PROCEDURAL ADJUSTMENTS IN CERTAIN CASES.**—In the case of applications described in subsection (a)(1) for financial assistance whose direct costs will not exceed \$50,000, the Administrator may make appropriate adjustments in the procedures otherwise established by the Administrator for the conduct of peer review under this section. Such adjustments may be made for the purpose of encouraging the entry of individuals into the field of research, for the purpose of encouraging clinical practice-oriented research, and for such other purposes as the Administrator may determine to be appropriate.

(e) **REGULATIONS.**—The Secretary shall issue regulations for the conduct of peer review under this section.

SEC. 923. [299c-2] CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA.

(a) **STANDARDS WITH RESPECT TO UTILITY OF DATA.**—

(1) **IN GENERAL.**—With respect to data developed or collected by any entity for the purpose described in section 901(b), the Administrator shall, in order to assure the utility, accuracy, and sufficiency of such data for all interested entities, establish guidelines for uniform methods of developing and collecting such data. Such guidelines shall include specifications for the development and collection of data on the outcomes of health care services and procedures.

(2) **RELATIONSHIP WITH MEDICARE PROGRAM.**—In any case where guidelines under paragraph (1) may affect the administration of the program under title XVIII of the Social Security Act, the guidelines shall be in the form of recommendations to the Secretary for such program.

(b) **STATISTICS.**—The Administrator shall—

(1) take such action as may be necessary to assure that statistics developed under this title are of high quality, timely, and comprehensive, as well as specific, standardized, and adequately analyzed and indexed; and

(2) publish, make available, and disseminate such statistics on as wide a basis as is practicable.

(c) **AUTHORITY REGARDING CERTAIN REQUESTS.**—Upon the request of a public or nonprofit private entity, the Administrator may tabulate and analyze statistics under arrangements under which such entity will pay the cost of the service provided. Amounts appropriated to the Administrator from payments made under such arrangements shall be available to the Administrator for obligation until expended.

SEC. 924. [299c-3] ADDITIONAL PROVISIONS WITH RESPECT TO GRANTS AND CONTRACTS.

(a) **FINANCIAL CONFLICTS OF INTEREST.**—With respect to projects for which awards of grants, cooperative agreements, or contracts are authorized to be made under this title, the Administrator shall by regulation define—

(1) the specific circumstances that constitute financial interests in such projects that will, or may be reasonably expected to, create a bias in favor of obtaining results in the projects that are consistent with such interests; and

(2) the actions that will be taken by the Administrator in response to any such interests identified by the Administrator.

(b) REQUIREMENT OF APPLICATION.—The Administrator may not, with respect to any program under this title authorizing the provision of grants, cooperative agreements, or contracts, provide any such financial assistance unless an application for the assistance is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Administrator determines to be necessary to carry out the program involved.

(c) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF FUNDS.—

(1) IN GENERAL.—Upon the request of an entity receiving a grant, cooperative agreement, or contract under this title, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the entity in carrying out the project involved and, for such purpose, may detail to the entity any officer or employee of the Department of Health and Human Services.

(2) CORRESPONDING REDUCTION IN FUNDS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of the financial assistance involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Administrator. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(d) APPLICABILITY OF CERTAIN PROVISIONS WITH RESPECT TO CONTRACTS.—Contracts may be entered into under this part without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

SEC. 925. [299c-4] CERTAIN ADMINISTRATIVE AUTHORITIES.

(a) DEPUTY ADMINISTRATOR AND OTHER OFFICERS AND EMPLOYEES.—

(1) DEPUTY ADMINISTRATOR.—The Administrator may appoint a deputy administrator for the Agency.

(2) OTHER OFFICERS AND EMPLOYEES.—The Administrator may appoint and fix the compensation of such officers and employees as may be necessary to carry out this title. Except as otherwise provided by law, such officers and employees shall be appointed in accordance with the civil service laws and their compensation fixed in accordance with title 5, United States Code.

(b) FACILITIES.—The Secretary, in carrying out this title—

(1) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or portions of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed 10 years; and

(2) may acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary.

(c) PROVISION OF FINANCIAL ASSISTANCE.—The Administrator, in carrying out this title, may make grants to, and enter into cooperative agreements with, public and nonprofit private entities and individuals, and when appropriate, may enter into contracts with public and private entities and individuals.

(d) UTILIZATION OF CERTAIN PERSONNEL AND RESOURCES.—

(1) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The Administrator, in carrying out this title, may utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, and provide technical assistance and advice.

(2) OTHER AGENCIES.—The Administrator, in carrying out this title, may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, or of any foreign government, with or without reimbursement of such agencies.

(e) CONSULTANTS.—The Secretary, in carrying out this title, may secure, from time to time and for such periods as the Administrator deems advisable but in accordance with section 3109 of title 5, United States Code, the assistance and advice of consultants from the United States or abroad.

(f) EXPERTS.—

(1) IN GENERAL.—The Secretary may, in carrying out this title, obtain the services of not more than 50 experts or consultants who have appropriate scientific or professional qualifications. Such experts or consultants shall be obtained in accordance with section 3109 of title 5, United States Code, except that the limitation in such section on the duration of service shall not apply.

(2) TRAVEL EXPENSES.—

(A) Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a)(1), 5724a(a)(3), and 5726(c) of title 5, United States Code.

(B) Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless and until the expert agrees in writing to complete the entire period of assignment, or one year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a debt

of the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(g) **VOLUNTARY AND UNCOMPENSATED SERVICES.**—The Administrator, in carrying out this title, may accept voluntary and uncompensated services.

SEC. 926. [299c-5] FUNDING.

(a) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this title, there are authorized to be appropriated \$115,000,000 for fiscal year 1993, \$145,000,000 for fiscal year 1994, and \$175,000,000 for fiscal year 1995.

(b) **EVALUATIONS.**—In addition to amounts available pursuant to subsection (a) for carrying out this title, there shall be made available for such purpose, from the amounts made available pursuant to section 241 of this Act (relating to evaluations), an amount equal to 40 percent of the maximum amount authorized in such section 241 to be made available.

(c) **INFORMATION CENTER.**—For purposes of carrying out the activities under section 903(e), there are authorized to be appropriated \$3,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 and 1995.

(d) **HEALTH CARE TECHNOLOGY ASSESSMENT.**—For the purpose of carrying out technology assessment activities under section 904(d), there are authorized to be appropriated \$2,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 and 1995.

(e) **PROGRAM OF INNOVATIVE ASSESSMENTS.**—For purposes of establishing the program of innovative assessments under section 904(f), there are authorized to be appropriated \$2,000,000 for fiscal year 1993, and such sums as may be necessary in each of the fiscal years 1994 and 1995.

SEC. 927. [299c-6] DEFINITIONS.

For purposes of this title:

(1) The term "Administrator" means the Administrator for Health Care Policy and Research.

(2) The term "Agency" means the Agency for Health Care Policy and Research.

(3) The term "Council" means the National Advisory Council on Health Care Policy, Research, and Evaluation.

(4) The term "Director" means the Director of the Office of the Forum for Quality and Effectiveness in Health Care.

TITLE X—POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES

SEC. 1001. [300] (a) The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection.

(b) In making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c) The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by the fair market value of any supplies or equipment furnished the grant recipient by the Secretary. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment on which the reduction of such grant is based. Such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(d) For the purpose of making grants and contracts under this section, there are authorized to be appropriated \$30,000,000 for the fiscal year ending June 30, 1971; \$60,000,000 for the fiscal year ending June 30, 1972; \$111,500,000 for the fiscal year ending June 30, 1973; \$111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; \$115,000,000 for fiscal year 1976; \$115,000,000 for the fiscal year ending September 30, 1977; \$136,400,000 for the fiscal year ending September 30, 1978; \$200,000,000 for the fiscal year ending September 30, 1979; \$230,000,000 for the fiscal year ending September 30, 1980; \$264,500,000 for the fiscal year ending September 30, 1981; \$126,510,000 for the fiscal year ending September 30, 1982; \$139,200,000 for the fiscal year ending September 30, 1983; \$150,030,000 for the fiscal year ending September 30, 1984; and \$158,400,000 for the fiscal year ending September 30, 1985.

FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES

SEC. 1002. [300a] (a) The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.

(b) The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.

(c) For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.

(d) For the purpose of making grants under this section, there are authorized to be appropriated \$10,000,000 for the fiscal year ending June 30, 1971; \$15,000,000 for the fiscal year ending June 30, 1972; and \$20,000,000 for the fiscal year ending June 30, 1973.

TRAINING GRANTS AND CONTRACTS

SEC. 1003. [300a-1] (a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 1001 or 1002.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated \$2,000,000 for the fiscal year ending June 30, 1971; \$3,000,000 for the fiscal year ending June 30, 1972; \$4,000,000 for the fiscal year ending June 30, 1973; and \$3,000,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; \$4,000,000 for fiscal year 1976; \$5,000,000 for the fiscal year ending September 30, 1977; \$3,000,000 for the fiscal year ending September 30, 1978; \$3,100,000 for the fiscal year ending September 30, 1979; \$3,600,000 for the fiscal year ending September 30, 1980; \$4,100,000 for the fiscal year ending September 30, 1981; \$2,920,000 for the fiscal year ending September 30, 1982; \$3,200,000 for the fiscal year ending September 30, 1983; \$3,500,000 for the fiscal year ending September 30, 1984; and \$3,500,000 for the fiscal year ending September 30, 1985.

RESEARCH

SEC. 1004. [300a-2] The Secretary may—

(1) conduct, and

(2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

INFORMATIONAL AND EDUCATIONAL MATERIALS

SEC. 1005. [300a-3] (a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials).

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated \$750,000 for the fiscal year ending June 30, 1971; \$1,000,000 for the fiscal year ending June 30, 1972; \$1,250,000 for the fiscal year ending June 30, 1973; \$909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; \$2,000,000 for fiscal year 1976; \$2,500,000 for the fiscal year ending September 30, 1977; \$600,000 for the fiscal year ending September 30, 1978; \$700,000 for the fiscal year ending September 30, 1979; \$805,000 for the fiscal year ending September 30, 1980; \$926,000 for the fiscal year ending September 30, 1981; \$570,000 for the fiscal year ending September 30, 1982; \$600,000 for the fiscal year ending September 30, 1983; \$670,000 for the fiscal year ending September 30, 1984; and \$700,000 for the fiscal year ending September 30, 1985.

REGULATIONS AND PAYMENTS

SEC. 1006. [300a-4] (a) Grants and contracts made under this title shall be made in accordance with such regulations as the Secretary may promulgate. The amount of any grant under any section of this title shall be determined by the Secretary; except that no grant under any such section for any program or project for a fiscal year beginning after June 30, 1975, may be made for less than 90 per centum of its costs (as determined under regulations of the Secretary) unless the grant is to be made for a program or project for which a grant was made (under the same section) for the fiscal year ending June 30, 1975, for less than 90 per centum of its costs (as so determined), in which case a grant under such section for that program or project for a fiscal year beginning after that date may be made for a percentage which shall not be less than the percentage of its costs for which the fiscal year 1975 grant was made.

(b) Grants under this title shall be payable in such installments and subject to such conditions as the Secretary may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made.

(c) A grant may be made or contract entered into under section 1001 or 1002 for a family planning service project or program only upon assurances satisfactory to the Secretary that—

(1) priority will be given in such project or program to the furnishing of such services to persons from low-income families; and

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party

(including a government agency) which is authorized or is under legal obligation to pay such charge.

For purposes of this subsection, the term "low-income family" shall be defined by the Secretary in accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

(d)(1) A grant may be made or a contract entered into under section 1001 or 1005 only upon assurances satisfactory to the Secretary that informational or educational materials developed or made available under the grant or contract will be suitable for the purposes of this title and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials.

(2) In the case of any grant or contract under section 1001, such assurances shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

VOLUNTARY PARTICIPATION

SEC. 1007. [300a-5] The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title (whether by grant or contract) shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

PROHIBITION OF ABORTION

SEC. 1008. [300a-6] None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

PLANS AND REPORTS

SEC. 1009. (a) Not later than seven months after the close of each fiscal year, the Secretary shall make a report to the Congress setting forth a plan to be carried out over the next five fiscal years for—

(1) extension of family planning services to all persons desiring such services,

(2) family planning and population research programs,

(3) training of necessary manpower for the programs authorized by this title and other Federal laws for which the Secretary has responsibility and which pertain to family planning, and

(4) carrying out the other purposes set forth in this title and the Family Planning Services and Population Research Act of 1970.

(b) Such a plan shall, at a minimum, indicate on a phased basis—

(1) the number of individuals to be served by family planning programs under this title and other Federal laws for which the Secretary has responsibility, the types of family planning and population growth information and educational materials to be developed under such laws and how they will be made available, the research goals to be reached under such laws, and the manpower to be trained under such laws;

(2) an estimate of the costs and personnel requirements needed to meet the purposes of this title and other Federal laws for which the Secretary has responsibility and which pertain to family planning programs; and

(3) the steps to be taken to maintain a systematic reporting system capable of yielding comprehensive data on which service figures and program evaluations for the Department of Health, Education, and Welfare shall be based.

(c) Each report submitted under subsection (a) shall—

(1) compare results achieved during the preceding fiscal year with the objectives established for such year under the plan contained in the previous such report;

(2) indicate steps being taken to achieve the objectives during the fiscal years covered by the plan contained in such report and any revisions to plans in previous reports necessary to meet these objectives; and

(3) make recommendations with respect to any additional legislative or administrative action necessary or desirable in carrying out the plan contained in such report.

TITLE XI—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME

PART A—GENETIC DISEASES

RESEARCH PROJECT GRANTS AND CONTRACTS

SEC. 1102. [300b-1] In carrying out section 301, the Secretary, may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for (1) basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases, (2) planning, establishing, demonstrating, and developing special programs for the training of genetic counselors, social and behavioral scientists, and other health professionals, (3) the development of programs to educate practicing physicians, other health professionals and the public regarding the nature of genetic processes, the inheritance patterns of genetic diseases, and the means, methods, and facilities available to diagnose, control, counsel, and treat genetic diseases, and (4) the development of counseling and testing programs and other programs for the diagnosis, control, and treatment of genetic diseases. In making grants and entering into contracts for projects described in clause (1) of the preceding sentence, the Secretary shall give priority to applications for such grants or contracts which are submitted for research on sickle cell anemia and for research on Cooley's anemia.

VOLUNTARY PARTICIPATION

SEC. 1103. [300b-2] The participation by any individual in any program or portion thereof under this part shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program.

APPLICATION; ADMINISTRATION OF GRANTS AND CONTRACT PROGRAMS

SEC. 1104. [300b-3] (a) A grant or contract under this part may be made upon application submitted to the Secretary at such time, in such manner, and containing and accompanied by such information, as the Secretary may require including assurances for an evaluation whether performed by the applicant or by the Secretary. Such grant or contract may be made available on less than a state-wide or regional basis. Each applicant shall—

(1) provide that the programs and activities for which assistance under this part is sought will be administered by or under the supervision of the applicant;

(2) provide for strict confidentiality of all test results, medical records, and other information regarding testing, diagnosis, counseling, or treatment of any person treated, except

for (A) such information as the patient (or his guardian) gives informed consent to be released, or (B) statistical data compiled without reference to the identity of any such patient;

(3) provide for community representation where appropriate in the development and operation of voluntary genetic testing or counseling programs funded by a grant or contract under this part; and

(4) establish fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting of Federal funds paid to the applicant under this part.

(b) In making grants and entering into contracts for any fiscal year under section 301 for projects described in section 1102 the Secretary shall give special consideration to applications from entities that received grants from, or entered into contracts with, the Secretary for the preceding fiscal year for the conduct of comprehensive sickle cell centers or sickle cell screening and education clinics.

PUBLIC HEALTH SERVICE FACILITIES

SEC. 1105. [300b-4] The Secretary shall establish a program within the Service to provide voluntary testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. Services under such program shall be made available through facilities of the Service to persons requesting such services, and the program shall provide appropriate publicity of the availability and voluntary nature of such services.

SEC. 1106. [Repealed].

APPLIED TECHNOLOGY

SEC. 1107. [300b-6] The Secretary, acting through an identifiable administrative unit, shall—

(1) conduct epidemiological assessments and surveillance of genetic diseases to define the scope and extent of such diseases and the need for programs for the diagnosis, treatment, and control of such diseases, screening for such diseases, and the counseling of persons with such diseases;

(2) on the basis of the assessments and surveillance described in paragraph (1), develop for use by the States programs which combine in an effective manner diagnosis, treatment, and control of such diseases, screening for such diseases, and counseling of persons with such diseases; and

(3) on the basis of the assessments and surveillance described in paragraph (1), provide technical assistance to States to implement the programs developed under paragraph (2) and train appropriate personnel for such programs.

In carrying out this section, the Secretary may, from funds allotted for use under section 502(a) of the Social Security Act, make grants to or contracts with public or nonprofit private entities (including grants and contracts for demonstration projects).

PART B—SUDDEN INFANT DEATH SYNDROME

SUDDEN INFANT DEATH SYNDROME RESEARCH AND RESEARCH REPORTS

SEC. 1122. [300c-12] (a) From the sums appropriated to the National Institute of Child Health and Human Development, the Secretary shall assure that there are applied to research of the type described in subparagraphs (A) and (B) of subsection (b)(1) of this section such amounts each year as will be adequate, given the leads and findings then available from such research, in order to make maximum feasible progress toward identification of infants at risk of sudden infant death syndrome and prevention of sudden infant death syndrome.

(b)(1) Not later than ninety days after the close of the fiscal year ending September 30, 1979, and of each fiscal year thereafter, the Secretary shall report to the Committees on Appropriations of the Senate and the House of Representatives, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives specific information for such fiscal year on—

(A) the (i) number of applications approved by the Secretary in the fiscal year reported on for grants and contracts under this Act for research which relates specifically to sudden infant death syndrome, (ii) total amount requested under such applications, (iii) number of such applications for which funds were provided in such fiscal year, and (iv) total amount of such funds; and

(B) the (i) number of applications approved by the Secretary in such fiscal year for grants and contracts under this Act for research which relates generally to sudden infant death syndrome, including high-risk pregnancy and high-risk infancy research which directly relates to sudden infant death syndrome, (ii) relationship of the high-risk pregnancy and high-risk infancy research to sudden infant death syndrome, (iii) total amount requested under such applications, (iv) number of such applications for which funds were provided in such fiscal year, and (v) total amount of such funds.

(2) Each report submitted under paragraph (1) of this subsection shall—

(A) contain a summary of the findings of intramural and extramural research supported by the National Institute of Child Health and Human Development relating to sudden infant death syndrome as described in subparagraphs (A) and (B) of such paragraph (1), and the plan of such Institute for taking maximum advantage of such research leads and findings; and

(B) provide an estimate of the need for additional funds over each of the next five fiscal years for grants and contracts under this Act for research activities described in such subparagraphs.

(c) Within five days after the Budget is transmitted by the President to the Congress for each fiscal year after fiscal year 1980, the Secretary shall transmit to the Committees on Appropriations of the Senate and the House of Representatives, the Committee on

Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives an estimate of the amounts requested for the National Institute of Child Health and Human Development and any other Institutes of the National Institutes of Health, respectively, for research relating to sudden infant death syndrome as described in subparagraphs (A) and (B) of subsection (b)(1) of this section, and a comparison of such amounts with the amounts requested for the preceding fiscal year.

PART C—HEMOPHILIA PROGRAMS

BLOOD SEPARATION CENTERS

SEC. 1132. [300c-22] (a) The Secretary may make grants to and enter into contracts with public and nonprofit private entities for projects to develop and expand, within existing facilities, blood-separation centers to separate and make available for distribution blood components to providers of blood services and manufacturers of blood fractions. For purposes of this section—

(1) the term "blood components" means those constituents of whole blood which are used for therapy and which are obtained by physical separation processes which result in licensed products such as red blood cells, platelets, white blood cells, AHF-rich plasma, fresh-frozen plasma, cryoprecipitate, and single unit plasma for infusion; and

(2) the term "blood fractions" means those constituents of plasma which are used for therapy and which are obtained by licensed fractionation processes presently used in manufacturing which result in licensed products such as normal serum albumin, plasma, protein fraction, prothrombin complex, fibrinogen, AHF concentrate, immune serum globulin, and hyperimmune globulins.

(b) In the event the Secretary finds that there is an insufficient supply of blood fractions available to meet the needs for treatment of persons suffering from hemophilia, and that public and other nonprofit private centers already engaged in the production of blood fractions could alleviate such insufficiency with assistance under this subsection, he may make grants not to exceed \$500,000 to such centers for the purposes of alleviating the insufficiency.

(c) No grant or contract may be made under subsection (a) or (b) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be in such form, submitted in such manner, and contain such information as the Secretary shall by regulation prescribe.

(d) Contracts may be entered into under subsection (a) without regard to section 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

(e) For the purpose of making payments under grants and contracts under subsections (a) and (b), there are authorized to be appropriated \$4,000,000 for fiscal year 1976, \$5,000,000 for the fiscal year ending September 30, 1977, \$3,450,000 for the fiscal year ending September 30, 1978, \$2,500,000 for the fiscal year ending September 30, 1979, \$3,000,000 for the fiscal year ending September 30, 1980, \$3,500,000 for the fiscal year ending September 30, 1981.

TITLE XII—TRAUMA CARE

PART A—GENERAL AUTHORITY AND DUTIES OF SECRETARY

SEC. 1201. [300d] ESTABLISHMENT.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall, with respect to trauma care—

(1) conduct and support research, training, evaluations, and demonstration projects;

(2) foster the development of appropriate, modern systems of such care through the sharing of information among agencies and individuals involved in the study and provision of such care;

(3) provide to State and local agencies technical assistance; and

(4) sponsor workshops and conferences.

(b) GRANTS, COOPERATIVE AGREEMENTS, AND CONTRACTS.—The Secretary may make grants, and enter into cooperative agreements and contracts, for the purpose of carrying out subsection (a).

(c) ADMINISTRATION.—The Administrator of the Health Resources and Services Administration shall ensure that this title is administered by the Division of Trauma and Emergency Medical Systems within such Administration. Such Division shall be headed by a director appointed by the Secretary from among individuals who are knowledgeable by training or experience in the development and operation of trauma and emergency medical systems.

SEC. 1202.¹ [300d-1] ADVISORY COUNCIL ON TRAUMA CARE SYSTEMS.

(a) ESTABLISHMENT.—The Secretary shall establish an advisory council to be known as the Advisory Council on Trauma Care Systems (hereafter in this section referred to as the ‘Council’).

(b) DUTIES.—The Council shall—

(1) periodically conduct assessments of the needs in the United States with respect to trauma care and the extent to which the States are responding to such needs, including special consideration of the unique needs of rural areas;

(2) submit to the Secretary the findings made as a result of such assessments; and

(3) advise the Secretary with respect to activities carried out under this title, including the development of the model trauma plan described in section 1213(c).

(c) MEMBERSHIP.—

¹Section 601(b) of Public Law 103-183 (107 Stat. 2238) provided that “Section 1201” is amended by striking section 1202 and redesignating sections 1203 and 1204 as sections 1202 and 1203, respectively. The amendment cannot be executed because section 1201 does not contain a section 1202, 1203, or 1204.

(1) IN GENERAL.—The Secretary shall appoint to the Council 12 appropriately qualified representatives of the public who are not officers or employees of the United States. Of such members—

(A) 3 shall be individuals experienced or specially trained in trauma surgery (including a critical care nurse);

(B) 3 shall be individuals experienced or specially trained in emergency medicine (including a nurse who is specially trained in emergency medicine);

(C) 1 shall be an individual experienced or specially trained in the care of injured children;

(D) 1 shall be an individual experienced or specially trained in physical medicine and rehabilitation; and

(E) 4 shall be individuals experienced or specially trained in the development, administration, or financing of trauma care systems.

(2) EX OFFICIO MEMBERS.—The Secretary may designate as ex officio members of the Council appropriately qualified representatives of the Department of Health and Human Services, the Department of Transportation, the Federal Emergency Management Agency, and such other agencies of the Federal Government as the Secretary determines to have functions affecting emergency medical services.

(3) KNOWLEDGE CONCERNING RURAL AREAS.—Of the members described in paragraph (1), 25 percent of the members shall be knowledgeable about the unique needs of rural areas with respect to the purpose of the Council.

(d) TERMS.—

(1) GENERAL TERM.—Except as provided in paragraph (2), members of the Council appointed under subsection (c)(1) shall serve for a term of 4 years.

(2) INITIAL MEMBERS.—Of the members first appointed to the Council under subsection (c)(1), the Secretary shall appoint 4 members to serve for a term of 4 years, 4 members to serve for a term of 3 years, and 4 members to serve for a term of 2 years.

(e) VACANCIES.—

(1) SERVICE FOR REMAINDER OF TERM.—Any member of the Council appointed under subsection (c)(1) to fill a vacancy occurring before the expiration of the term of the predecessor of the member shall be appointed for the remainder of the term of the predecessor.

(2) CONTINUED SERVICE AFTER EXPIRATION OF TERM.—A member of the Council appointed under subsection (c)(1) may continue to serve after the expiration of the term of the member until a successor is appointed.

(f) CHAIR.—The Secretary, or the designee of the Secretary, shall serve as the chair of the Council.

(g) MEETINGS.—The Council shall meet at the call of the Chair and shall meet not less than once each 3 months.

(h) COMPENSATION AND REIMBURSEMENT OF EXPENSES.—

(1) FEDERAL OFFICIALS.—Ex officio members of the Council under subsection (c)(2) may not receive compensation for service on the Council in addition to the compensation otherwise

received for duties carried out as officers or employees of the United States.

(2) **APPOINTMENT MEMBERS.**—Members of the Council appointed under subsection (c)(1) may not receive compensation for service on the Council. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Council.

(i) **STAFF.**—The Secretary shall provide to the Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

(j) **TERMINATION.**—Notwithstanding section 14(a) of the Federal Advisory Committee Act, the Council shall continue in existence until otherwise provided by law.

SEC. 1203.¹ [300d-2] CLEARINGHOUSE ON TRAUMA CARE AND EMERGENCY MEDICAL SERVICES.

(a) **ESTABLISHMENT.**—The Secretary shall by contract provide for the establishment and operation of a National Clearinghouse on Trauma Care and Emergency Medical Services (hereafter in this section referred to as the “Clearinghouse”).

(b) **DUTIES.**—The Clearinghouse shall—

(1) foster the development of appropriate, modern trauma care and emergency medical services (including the development of policies for the notification of family members of individuals involved in medical emergencies) through the sharing of information among agencies and individuals involved in planning, furnishing, and studying such services and care;

(2) collect, compile, and disseminate information on the achievements of, and problems experienced by, State and local agencies and private entities in providing trauma care and emergency medical services and, in so doing, give special consideration of the unique needs of rural areas;

(3) provide technical assistance relating to trauma care and emergency medical services to State and local agencies; and

(4) sponsor workshops and conferences on trauma care and emergency medical services.

(c) **FEES AND ASSESSMENTS.**—A contract entered into by the Secretary under this section may provide that the Clearinghouse charge fees or assessments in order to defray, and beginning with fiscal year 1992, to cover, the costs of operating the Clearinghouse.

SEC. 1204.¹ [300d-3] ESTABLISHMENT OF PROGRAMS FOR IMPROVING TRAUMA CARE IN RURAL AREAS.

(a) **IN GENERAL.**—The Secretary may make grants to public and nonprofit private entities for the purpose of carrying out research and demonstration projects with respect to improving the availability and quality of emergency medical services in rural areas—

(1) by developing innovative uses of communications technologies and the use of new communications technology;

(2) by developing model curricula for training emergency medical services personnel, including first responders, emer-

¹ See footnote 1 on page 604.

gency medical technicians, emergency nurses and physicians, and paramedics—

(A) in the assessment, stabilization, treatment, preparation for transport, and resuscitation of seriously injured patients, with special attention to problems that arise during long transports and to methods of minimizing delays in transport to the appropriate facility; and

(B) in the management of the operation of the emergency medical services system;

(3) by making training for original certification, and continuing education, in the provision and management of emergency medical services more accessible to emergency medical personnel in rural areas through telecommunications, home studies, providing teachers and training at locations accessible to such personnel, and other methods;

(4) by developing innovative protocols and agreements to increase access to prehospital care and equipment necessary for the transportation of seriously injured patients to the appropriate facilities; and

(5) by evaluating the effectiveness of protocols with respect to emergency medical services and systems.

(b) SPECIAL CONSIDERATION FOR CERTAIN RURAL AREAS.—In making grants under subsection (a), the Secretary shall give special consideration to any applicant for the grant that will provide services under the grant in any rural area identified by a State under section 1214(c)(1).

(c) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

PART B—FORMULA GRANTS WITH RESPECT TO MODIFICATIONS OF STATE PLANS

SEC. 1211. [300d-11] ESTABLISHMENT OF PROGRAM.

(a) REQUIREMENT OF ALLOTMENTS FOR STATES.—The Secretary shall for each fiscal year make an allotment for each State in an amount determined in accordance with section 1218. The Secretary shall make payments, as grants, each fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 1217.

(b) PURPOSE.—Except as provided in section 1233, the Secretary may not make payments under this part for a fiscal year unless the State involved agrees that, with respect to the trauma care component of the State plan for the provision of emergency medical services, the payments will be expended only for the purpose of developing, implementing, and monitoring the modifications to such component described in section 1213.

SEC. 1212. [300d-12] REQUIREMENT OF MATCHING FUNDS FOR FISCAL YEARS SUBSEQUENT TO FIRST FISCAL YEAR OF PAYMENTS.**(a) NON-FEDERAL CONTRIBUTIONS.—**

(1) **IN GENERAL.**—The Secretary may not make payments under section 1211(a) unless the State involved agrees, with respect to the costs described in paragraph (2), to make available non-Federal contributions (in cash or in kind under subsection (b)(1)) toward such costs in an amount equal to—

(A) for the second fiscal year of such payments to the State, not less than \$1 for each \$1 of Federal funds provided in such payments for such fiscal year; and

(B) for any subsequent fiscal year of such payments to the State, not less than \$3 for each \$1 of Federal funds provided in such payments for such fiscal year.

(2) **PROGRAM COSTS.**—The costs referred to in paragraph

(1) are—

(A) the costs to be incurred by the State in carrying out the purpose described in section 1211(b); or

(B) the costs of improving the quality and availability of emergency medical services in rural areas of the State.

(3) **INITIAL YEAR OF PAYMENTS.**—The Secretary may not require a State to make non-Federal contributions as a condition of receiving payments under section 1211(a) for the first fiscal year of such payments to the State.

(b) **DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.**—With respect to compliance with subsection (a) as a condition of receiving payments under section 1211(a)—

(1) a State may make the non-Federal contributions required in such subsection in cash or in kind, fairly evaluated, including plant, equipment, or services;

(2) the Secretary may not, in making a determination of the amount of non-Federal contributions, include amounts provided by the Federal Government or services assisted or subsidized to any significant extent by the Federal Government; and

(3) the Secretary shall, in making such a determination, include only non-Federal contributions in excess of the amount of non-Federal contributions made by the State during fiscal year 1990 toward—

(A) the costs of providing trauma care in the State; and

(B) the costs of improving the quality and availability of emergency medical services in rural areas of the State.

SEC. 1213. [300d-13] REQUIREMENTS WITH RESPECT TO CARRYING OUT PURPOSE OF ALLOTMENTS.

(a) **TRAUMA CARE MODIFICATIONS TO STATE PLAN FOR EMERGENCY MEDICAL SERVICES.**—With respect to the trauma care component of a State plan for the provision of emergency medical services, the modifications referred to in section 1211(b) are such modifications to the State plan as may be necessary for the State involved to ensure that the plan provides for access to the highest possible quality of trauma care, and that the plan—

(1) specifies that the modifications required pursuant to paragraphs (2) through (10) will be implemented by the principal State agency with respect to emergency medical services or by the designee of such agency;

(2) specifies any public or private entity that will designate trauma care regions and trauma centers in the State;

(3) subject to subsection (b), contains standards and requirements for the designation of level I and level II trauma centers, and in the case of rural areas level III trauma centers (including trauma centers with specified capabilities and expertise in the care of the pediatric trauma patient), by such entity, including standards and requirements for—

(A) the number and types of trauma patients for whom such centers must provide care in order to ensure that such centers will have sufficient experience and expertise to be able to provide quality care for victims of injury;

(B) the resources and equipment needed by such centers; and

(C) the availability of rehabilitation services for trauma patients;

(4) subject to subsection (b), contains standards and requirements for the implementation of regional trauma care systems, including standards and guidelines (consistent with the provisions of section 1867 of the Social Security Act) for medically directed triage and transportation of trauma patients (including patients injured in rural areas) prior to care in designated trauma centers;

(5) subject to subsection (b), contains standards and requirements for medically directed triage and transport of severely injured children to designated trauma centers with specified capabilities and expertise in the care of the pediatric trauma patient;

(6) specifies procedures for the evaluation of designated trauma centers (including trauma centers described in paragraph (5)) and trauma care systems;

(7) provides for the establishment and collection of data from each designated trauma center in the State of a central data reporting and analysis system—

(A) to identify the number of severely injured trauma patients within regional trauma care systems in the State;

(B) to identify the cause of the injury and any factors contributing to the injury;

(C) to identify the nature and severity of the injury;

(D) to monitor trauma patient care (including prehospital care) in each designated trauma center within regional trauma care systems in the State (including relevant emergency-department discharges and rehabilitation information) for the purpose of evaluating the diagnosis, treatment and treatment outcome of such trauma patients;

(E) to identify the total amount of uncompensated trauma care expenditures for each fiscal year by each designated trauma center in the State; and

(F) to identify patients transferred within a regional trauma system, including reasons for such transfer;

(8) provides for for¹ the use of procedures by paramedics and emergency medical technicians to assess the severity of the injuries incurred by trauma patients;

(9) provides for appropriate transportation and transfer policies to ensure the delivery of patients to designated trauma centers and other facilities within and outside of the jurisdiction of such system, including policies to ensure that only individuals appropriately identified as trauma patients are transferred to designated trauma centers, and to provide periodic reviews of the transfers and the auditing of such transfers that are determined to be appropriate;

(10) conducts public education activities concerning injury prevention and obtaining access to trauma care; and

(11) with respect to the requirements established in this subsection, provides for coordination and cooperation between the State and any other State with which the State shares any standard metropolitan statistical area.

(b) CERTAIN STANDARDS WITH RESPECT TO TRAUMA CARE CENTERS AND SYSTEMS.—

(1) IN GENERAL.—The Secretary may not make payments under section 1211(a) for a fiscal year unless the State involved agrees that, in carrying out paragraphs (3) through (5) of subsection (a), the State will adopt standards for the designation of trauma centers, and for triage, transfer, and transportation policies, and that the State will, in adopting such standards—

(A) take into account national standards concerning such;

(B) consult with medical, surgical, and nursing specialty groups, hospital associations, emergency medical services State and local directors, concerned advocates and other interested parties;

(C) conduct hearings on the proposed standards after providing adequate notice to the public concerning such hearing; and

(D) beginning in fiscal year 1992, take into account the model plan described in subsection (c).

(2) QUALITY OF TRAUMA CARE.—The highest quality of trauma care shall be the primary goal of State standards adopted under this subsection.

(3) APPROVAL BY SECRETARY.—The Secretary may not make payments under section 1211(a) to a State if the Secretary determines that—

(A) in the case of payments for fiscal year 1991 and subsequent fiscal years, the State has not taken into account national standards, including those of the American College of Surgeons, the American College of Emergency Physicians and the American Academy of Pediatrics, in adopting standards under this subsection; or

(B) in the case of payments for fiscal year 1992 and subsequent fiscal years, the State has not, in adopting

¹ So in original. See section 601(f)(3)(B) of Public Law 103-183 (107 Stat. 2239).

such standards, taken into account the model plan developed under subsection (c) .

(c) **MODEL TRAUMA CARE PLAN.**—Not later than 1 year after the date of the enactment of the Trauma Care Systems Planning and Development Act of 1990¹, the Secretary shall develop a model plan for the designation of trauma centers and for triage, transfer and transportation policies that may be adopted for guidance by the State. Such plan shall—

(1) take into account national standards, including those of the American College of Surgeons, American College of Emergency Physicians and the American Academy of Pediatrics;

(2) take into account existing State plans;

(3) be developed in consultation with medical, surgical, and nursing speciality groups, hospital associations, emergency medical services State directors and associations, and other interested parties; and

(4) include standards for the designation of rural health facilities and hospitals best able to receive, stabilize, and transfer trauma patients to the nearest appropriate designated trauma center, and for triage, transfer, and transportation policies as they relate to rural areas.

Standards described in paragraph (4) shall be applicable to all rural areas in the State, including both non-metropolitan areas and frontier areas that have populations of less than 6,000 per square mile.

(d) **RULE OF CONSTRUCTION WITH RESPECT TO NUMBER OF DESIGNATED TRAUMA CENTERS.**—With respect to compliance with subsection (a) as a condition of the receipt of a grant under section 1211(a), such subsection may not be construed to specify the number of trauma care centers designated pursuant to such subsection.

SEC. 1214. [300d-14] REQUIREMENT OF SUBMISSION TO SECRETARY OF TRAUMA PLAN AND CERTAIN INFORMATION.

(a) **TRAUMA PLAN.**—

(1) **IN GENERAL.**—For fiscal year 1991 and subsequent fiscal years, the Secretary may not make payments under section 1211(a) unless, subject to paragraph (2), the State involved submits to the Secretary the trauma care component of the State plan for the provision of emergency medical services.

(2) **INTERIM PLAN OR DESCRIPTION OF EFFORTS.**—For fiscal year 1991, if a State has not completed the trauma care component of the State plan described in paragraph (1), the State may provide, in lieu of a completed such component, an interim component or a description of efforts made toward the completion of the component.

(b) **INFORMATION RECEIVED BY STATE REPORTING AND ANALYSIS SYSTEM.**—The Secretary may not make payments under section 1211(a) for a fiscal year unless the State involved agrees that the State will, not less than once each year, provide to the Secretary the information received by the State pursuant to section 1213(a)(7).

¹Enacted November 16, 1990.

(c) AVAILABILITY OF EMERGENCY MEDICAL SERVICES IN RURAL AREAS.—The Secretary may not make payments under section 1211(a) for a fiscal year unless—

(1) the State involved identifies any rural area in the State for which—

(A) there is no system of access to emergency medical services through the telephone number 911;

(B) there is no basic life-support system; or

(C) there is no advanced life-support system; and

(2) the State submits to the Secretary a list of rural areas identified pursuant to paragraph (1) or, if there are no such areas, a statement that there are no such areas.

SEC. 1215. [300d-15] RESTRICTIONS ON USE OF PAYMENTS.

(a) IN GENERAL.—The Secretary may not, except as provided in subsection (b), make payments under section 1211(a) for a fiscal year unless the State involved agrees that the payments will not be expended—

(1) subject to section 1233, for any purpose other than developing, implementing, and monitoring the modifications required by section 1211(b) to be made to the State plan for the provision of emergency medical services.¹

(2) to make cash payments to intended recipients of services provided pursuant to such section;

(3) to purchase or improve real property (other than minor remodeling of existing improvements to real property) or to purchase major medical or communication equipment, ambulances, or aircraft;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(b) EXCEPTION.—If the Secretary finds that the purpose described in section 1211(b) cannot otherwise be carried out, the Secretary may, with respect to an otherwise qualified State, waive the restriction established in subsection (a)(3).

SEC. 1216. [300d-16] REQUIREMENT OF REPORTS BY STATES.

(a) IN GENERAL.—The Secretary may not make payments under section 1211(a) for a fiscal year unless the State involved agrees to prepare and submit to the Secretary an annual report in such form and containing such information as the Secretary determines (after consultation with the States and the Comptroller General of the United States) to be necessary for—

(1) securing a record and a description of the purposes for which payments received by the State pursuant to such section were expended and of the recipients of such payments; and

(2) determining whether the payments were expended in accordance with the purpose of the program involved.

(b) AVAILABILITY TO PUBLIC OF REPORTS.—The Secretary may not make payments under section 1211(a) unless the State involved

¹ So in original. See Public Law 101-590. Probably should be a semicolon.

agrees that the State will make copies of the report described in subsection (a) available for public inspection.

(c) **EVALUATIONS BY COMPTROLLER GENERAL.**—The Comptroller General of the United States shall evaluate the expenditures by States of payments under section 1211(a) in order to assure that expenditures are consistent with the provisions of this part, and not later than December 1, 1994, prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report concerning such evaluation.

SEC. 1217. [300d-17] REQUIREMENT OF SUBMISSION OF APPLICATION CONTAINING CERTAIN AGREEMENTS AND ASSURANCES.

The Secretary may not make payments under section 1211(a) to a State for a fiscal year unless—

(1) the State submits to the Secretary an application for the payments containing agreements in accordance with this part;

(2) the agreements are made through certification from the chief executive officer of the State;

(3) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary;

(4) the application contains the plan provisions and the information required to be submitted to the Secretary pursuant to section 1214; and

(5) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

SEC. 1218. [300d-18] DETERMINATION OF AMOUNT OF ALLOTMENT.

(a) **MINIMUM ALLOTMENT.**—Subject to the extent of amounts made available in appropriations Acts, the amount of an allotment under section 1211(a) for a State for a fiscal year shall be the greater of—

(1) the amount determined under subsection (b)(1); and

(2) \$250,000 in the case of each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, and \$50,000 in the case of each of the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(b) **DETERMINATION UNDER FORMULA.**—

(1) **IN GENERAL.**—The amount referred to in subsection (a)(1) for a State for a fiscal year is the sum of—

(A) an amount determined under paragraph (2); and

(B) an amount determined under paragraph (3).

(2) **AMOUNT RELATING TO POPULATION.**—The amount referred to in subparagraph (A) of paragraph (1) for a State for a fiscal year is the product of—

(A) an amount equal to 80 percent of the amounts appropriated under section 1232(a) for the fiscal year and available for allotment under section 1211(a); and

(B) a percentage equal to the quotient of—

(i) an amount equal to the population of the State; divided by

(ii) an amount equal to the population of all States.

(3) AMOUNT RELATING TO SQUARE MILEAGE.—The amount referred to in subparagraph (B) of paragraph (1) for a State for a fiscal year is the product of—

(A) an amount equal to 20 percent of the amounts appropriated under section 1232(a) for the fiscal year and available for allotment under section 1211(a); and

(B) a percentage equal to the quotient of—

(i) an amount equal to the lesser of 266,807 and the amount of the square mileage of the State; divided by

(ii) an amount equal to the sum of the respective amounts determined for the States under clause (i).

(c) DISPOSITION OF CERTAIN FUNDS APPROPRIATED FOR ALLOTMENTS.—

(1) IN GENERAL.—Amounts described in paragraph (2) shall, in accordance with paragraph (3), be allotted by the Secretary to States receiving payments under section 1211(a) for the fiscal year (other than any State referred to in paragraph (2)(C)).

(2) TYPE OF AMOUNTS.—The amounts referred to in paragraph (1) are any amounts made available pursuant to 1232(b)(3) that are not paid under section 1211(a) to a State as a result of—

(A) the failure of the State to submit an application under section 1217;

(B) the failure, in the determination of the Secretary, of the State to prepare within a reasonable period of time such application in compliance with such section; or

(C) the State informing the Secretary that the State does not intend to expend the full amount of the allotment made for the State.

(3) AMOUNT.—The amount of an allotment under paragraph (1) for a State for a fiscal year shall be an amount equal to the product of—

(A) an amount equal to the amount described in paragraph (2) for the fiscal year involved; and

(B) the percentage determined under subsection (b)(2) for the State.

SEC. 1219. [300d-19] FAILURE TO COMPLY WITH AGREEMENTS.

(a) REPAYMENT OF PAYMENTS.—

(1) REQUIREMENT.—The Secretary may, in accordance with subsection (b), require a State to repay any payments received by the State pursuant to section 1211(a) that the Secretary determines were not expended by the State in accordance with the agreements required to be made by the State as a condition of the receipt of payments under such section.

(2) OFFSET OF AMOUNTS.—If a State fails to make a repayment required in paragraph (1), the Secretary may offset the

amount of the repayment against any amount due to be paid to the State under section 1211(a).

(b) OPPORTUNITY FOR A HEARING.—Before requiring repayment of payments under subsection (a)(1), the Secretary shall provide to the State an opportunity for a hearing.

SEC. 1220. [300d-20] PROHIBITION AGAINST CERTAIN FALSE STATEMENTS.

(a) IN GENERAL.—

(1) FALSE STATEMENTS OR REPRESENTATIONS.—A person may not knowingly and willfully make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which payments may be made by a State from amounts paid to the State under section 1211(a).

(2) CONCEALING OR FAILING TO DISCLOSE INFORMATION.—A person with knowledge of the occurrence of any event affecting the right of the person to receive any payments from amounts paid to the State under section 1211(a) may not conceal or fail to disclose any such event with the intent of fraudulently securing such amount.

(b) CRIMINAL PENALTY FOR VIOLATION OF PROHIBITION.—Any person who violates a prohibition established in subsection (a) may for each violation be fined in accordance with title 18, United States Code, or imprisoned for not more than 5 years, or both.

SEC. 1221. [300d-21] TECHNICAL ASSISTANCE AND PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) TECHNICAL ASSISTANCE.—The Secretary shall, without charge to a State receiving payments under section 1211(a), provide to the State (or to any public or nonprofit private entity designated by the State) technical assistance with respect to the planning, development, and operation of any program carried out pursuant to section 1211(b). The Secretary may provide such technical assistance directly, through contract, or through grants.

(b) PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) IN GENERAL.—Upon the request of a State receiving payments under section 1211(a), the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out section 1211(b) and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) REDUCTION IN PAYMENTS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments to the State under section 1211(a) by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 1222. [300d-22] REPORT BY SECRETARY.

Not later than October 1, 1995, the Secretary shall report to the appropriate committees of Congress on the activities of the

States carried out pursuant to section 1211. Such report shall include an assessment of the extent to which Federal and State efforts to develop systems of trauma care and to designate trauma centers have reduced the incidence of mortality, and the incidence of permanent disability, resulting from trauma. Such report may include any recommendations of the Secretary for appropriate administrative and legislative initiatives with respect to trauma care.

PART C—GENERAL PROVISIONS REGARDING PARTS A AND B

SEC. 1231. [300d-31] DEFINITIONS.

For purposes of this part and parts A and B:

(1) DESIGNATED TRAUMA CENTER.—The term “designated trauma center” means a trauma center designated in accordance with the modifications to the State plan described in section 1213.

(2) STATE PLAN REGARDING EMERGENCY MEDICAL SERVICES.—The term “State plan”, with respect to the provision of emergency medical services, means a plan for a comprehensive, organized system to provide for the access, response, triage, field stabilization, transport, hospital stabilization, definitive care, and rehabilitation of patients of all ages with respect to emergency medical services.

(3) STATE.—The term “State” means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(4) TRAUMA.—The term “trauma” means an injury resulting from exposure to a mechanical force.

(5) TRAUMA CARE COMPONENT OF STATE PLAN.—The term “trauma care component”, with respect to components of the State plan for the provision of emergency medical services, means a plan for a comprehensive health care system, within rural and urban areas of the State, for the prompt recognition, prehospital care, emergency medical care, acute surgical and medical care, rehabilitation, and outcome evaluation of seriously injured patients.

SEC. 1232. [300d-32] FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out parts A and B, there are authorized to be appropriated \$6,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

(b) ALLOCATION OF FUNDS BY SECRETARY.—

(1) GENERAL AUTHORITY.—For the purpose of carrying out part A, the Secretary shall make available 10 percent of the amounts appropriated for a fiscal year under subsection (a).

(2) RURAL GRANTS.—For the purpose of carrying out section 1204, the Secretary shall make available 10 percent of the amounts appropriated for a fiscal year under subsection (a).

(3) FORMULA GRANTS.—

(A) For the purpose of making allotments under section 1211(a), the Secretary shall, subject to subsection (c), make available 80 percent of the amounts appropriated for a fiscal year pursuant to subsection (a).

(B) Amounts paid to a State under section 1211(a) for a fiscal year shall, for the purposes for which the amounts were paid, remain available for obligation until the end of the fiscal year immediately following the fiscal year for which the amounts were paid.

(c) EFFECT OF INSUFFICIENT APPROPRIATIONS FOR MINIMUM ALLOTMENTS.—

(1) IN GENERAL.—If the amounts made available under subsection (b)(3)(A) for a fiscal year are insufficient for providing each State with an allotment under section 1211(a) of not less than the applicable amount under section 1218(a)(2), the Secretary shall, from such amounts as are made available under subsection (b)(3)(A), make grants to States described in paragraph (2) for carrying out part B.

(2) ELIGIBLE STATES.—The States referred to in paragraph (1) are States that—

(A) have the greatest need to develop, implement, and maintain trauma care systems; and

(B) demonstrate in their applications under section 1217 the greatest commitment to establishing and maintaining such systems.

(3) RULE OF CONSTRUCTION.—Paragraph (1) may not be construed to require the Secretary to make a grant under such paragraph to each State.

PART D—TRAUMA CENTERS OPERATING IN AREAS SEVERELY AFFECTED BY DRUG-RELATED VIOLENCE

SEC. 1241. [300d-41] GRANTS FOR CERTAIN TRAUMA CENTERS.

(a) IN GENERAL.—The Secretary may make grants for the purpose of providing for the operating expenses of trauma centers that have incurred substantial uncompensated costs in providing trauma care in geographic areas with a significant incidence of violence arising directly or indirectly from illicit trafficking in drugs. Grants under this subsection may be made only to such trauma centers.

(b) MINIMUM QUALIFICATIONS OF CENTERS.—

(1) SIGNIFICANT INCIDENCE OF TREATING CERTAIN PATIENTS.—

(A) The Secretary may not make a grant under subsection (a) to a trauma center unless the population of patients that has been served by the center for the period specified in subparagraph (B) includes a significant number of patients who were treated for—

(i) trauma resulting from the penetration of the skin by knives, bullets, or any other implement that can be used as a weapon; or

(ii) trauma that the center reasonably believes results from violence arising directly or indirectly from illicit trafficking in drugs.

(B) The period specified in this subparagraph is the 2-year period preceding the fiscal year for which the trauma center involved is applying to receive a grant under subsection (a).

(2) PARTICIPATION IN TRAUMA CARE SYSTEM OPERATING UNDER CERTAIN PROFESSIONAL GUIDELINES.—The Secretary may not make a grant under subsection (a) unless the trauma center involved is a participant in a system that—

(A) provides comprehensive medical care to victims of trauma in the geographic area in which the trauma center is located;

(B) is established by the State or political subdivision in which such center is located; and

(C)(i) has adopted guidelines for the designation of trauma centers, and for triage, transfer, and transportation policies, equivalent to (or more protective than) the applicable guidelines developed by the American College of Surgeons or utilized in the model plan established under section 1213(c); or

(ii) agrees that such guidelines will be adopted by the system not later than 6 months after the date on which the trauma center submits to the Secretary the application for the grant.

(3) SUBMISSION AND APPROVAL OF LONG-TERM PLAN.—The Secretary may not make a grant under subsection (a) unless the trauma center involved—

(A) submits to the Secretary a plan satisfactory to the Secretary that—

(i) is developed on the assumption that the center will continue to incur substantial uncompensated costs in providing trauma care; and

(ii) provides for the long-term continued operation of the center with an acceptable standard of medical care, notwithstanding such uncompensated costs; and

(B) agrees to implement the plan according to a schedule approved by the Secretary.

SEC. 1242. [300d-42] PREFERENCES IN MAKING GRANTS.

(a) IN GENERAL.—In making grants under section 1241(a), the Secretary shall give preference to any application—

(1) made by a trauma center that, for the purpose specified in such section, will receive financial assistance from the State or political subdivision involved for each fiscal year during which payments are made to the center from the grant, which financial assistance is exclusive of any assistance provided by the State or political subdivision as a non-Federal contribution under any Federal program requiring such a contribution; or

(2) made by a trauma center that, with respect to the system described in section 1241(b)(2) in which the center is a participant—

(A) is providing trauma care in a geographic area in which the availability of trauma care has significantly decreased as a result of a trauma center in the area permanently ceasing participation in such system as of a date occurring during the 2-year period specified in section 1241(b)(1)(B); or

(B) will, in providing trauma care during the 1-year period beginning on the date on which the application for

the grant is submitted, incur uncompensated costs in an amount rendering the center unable to continue participation in such system, resulting in a significant decrease in the availability of trauma care in the geographic area.

(b) **FURTHER PREFERENCE FOR CERTAIN APPLICATIONS.**—With respect to applications for grants under section 1241 that are receiving preference for purposes of subsection (a), the Secretary shall give further preference to any such application made by a trauma center for which a disproportionate percentage of the uncompensated costs of the center result from the provision of trauma care to individuals who neither are citizens nor aliens lawfully admitted to the United States for permanent residence.

SEC. 1243. [300d-43] CERTAIN AGREEMENTS.

(a) **COMMITMENT REGARDING CONTINUED PARTICIPATION IN TRAUMA CARE SYSTEM.**—The Secretary may not make a grant under subsection (a) of section 1241 unless the trauma center involved agrees that—

(1) the center will continue participation in the system described in subsection (b) of such section throughout the 3-year period beginning on the date that the center first receives payments under the grant; and

(2) if the agreement made pursuant to paragraph (1) is violated by the center, the center will be liable to the United States for an amount equal to the sum of—

(A) the amount of assistance provided to the center under subsection (a) of such section; and

(B) an amount representing interest on the amount specified in subparagraph (A).

(b) **MAINTENANCE OF FINANCIAL SUPPORT.**—With respect to activities for which a grant under section 1241 is authorized to be expended, the Secretary may not make such a grant unless the trauma center involved agrees that, during the period in which the center is receiving payments under the grant, the center will maintain expenditures for such activities at a level that is not less than the level maintained by the center during the fiscal year preceding the first fiscal year for which the center receives such payments.

(c) **TRAUMA CARE REGISTRY.**—The Secretary may not make a grant under section 1241(a) unless the trauma center involved agrees that—

(1) the center will operate a registry of trauma cases in accordance with the applicable guidelines described in section 1241(b)(2)(C), and will begin operation of the registry not later than 6 months after the date on which the center submits to the Secretary the application for the grant; and

(2) in carrying out paragraph (1), the center will maintain information on the number of trauma cases treated by the center and, for each such case, the extent to which the center incurs uncompensated costs in providing trauma care.

SEC. 1244. [300d-44] GENERAL PROVISIONS.

(a) **APPLICATION.**—The Secretary may not make a grant under section 1241(a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and informa-

tion as the Secretary determines to be necessary to carry out this part.

(b) **LIMITATION ON DURATION OF SUPPORT.**—The period during which a trauma center receives payments under section 1241(a) may not exceed 3 fiscal years, except that the Secretary may waive such requirement for the center and authorize the center to receive such payments for 1 additional fiscal year.

(c) **LIMITATION ON AMOUNT OF GRANT.**—A grant under section 1241 may not be made in an amount exceeding \$2,000,000.

SEC. 1245. [300d-45] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there are authorized to be appropriated \$100,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994. Such authorization of appropriations is in addition to any other authorization of appropriations or amounts that are available for such purpose.

Part E—Miscellaneous Programs ¹

SEC. 1251. [300d-51] RESIDENCY TRAINING PROGRAMS IN EMERGENCY MEDICINE.

(a) **IN GENERAL.**—The Secretary may make grants to public and nonprofit private entities for the purpose of planning and developing approved residency training programs in emergency medicine.

(b) **IDENTIFICATION AND REFERRAL OF DOMESTIC VIOLENCE.**—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that training programs under subsection (a) will provide education and training in identifying and referring cases of domestic violence.

(c) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there is authorized to be appropriated \$400,000 for each of the fiscal years 1993 through 1995.

PART F—INTERAGENCY PROGRAM FOR TRAUMA RESEARCH

SEC. 1261. [300d-61] ESTABLISHMENT OF PROGRAM.

(a) **IN GENERAL.**—The Secretary, acting through the Director of the National Institutes of Health (in this section referred to as the “Director”), shall establish a comprehensive program of conducting basic and clinical research on trauma (in this section referred to as the “Program”). The Program shall include research regarding the diagnosis, treatment, rehabilitation, and general management of trauma.

(b) **PLAN FOR PROGRAM.**—

(1) **IN GENERAL.**—The Director, in consultation with the Trauma Research Interagency Coordinating Committee established under subsection (g), shall establish and implement a plan for carrying out the activities of the Program, including the activities described in subsection (d). All such activities shall be carried out in accordance with the plan. The plan shall be periodically reviewed, and revised as appropriate.

¹ So in original. Typeface and capitalization is inconsistent with the other parts in this title.

(2) SUBMISSION TO CONGRESS.—Not later than December 1, 1993, the Director shall submit the plan required in paragraph (1) to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, together with an estimate of the funds needed for each of the fiscal years 1994 through 1996 to implement the plan.

(c) PARTICIPATING AGENCIES; COORDINATION AND COLLABORATION.—The Director—

(1) shall provide for the conduct of activities under the Program by the Directors of the agencies of the National Institutes of Health involved in research with respect to trauma;

(2) shall ensure that the activities of the Program are coordinated among such agencies; and

(3) shall, as appropriate, provide for collaboration among such agencies in carrying out such activities.

(d) CERTAIN ACTIVITIES OF PROGRAM.—The Program shall include—

(1) studies with respect to all phases of trauma care, including prehospital, resuscitation, surgical intervention, critical care, infection control, wound healing, nutritional care and support, and medical rehabilitation care;

(2) basic and clinical research regarding the response of the body to trauma and the acute treatment and medical rehabilitation of individuals who are the victims of trauma; and

(3) basic and clinical research regarding trauma care for pediatric and geriatric patients.

(e) MECHANISMS OF SUPPORT.—In carrying out the Program, the Director, acting through the Directors of the agencies referred to in subsection (c)(1), may make grants to public and nonprofit entities, including designated trauma centers.

(f) RESOURCES.—The Director shall assure the availability of appropriate resources to carry out the Program, including the plan established under subsection (b) (including the activities described in subsection (d)).

(g) COORDINATING COMMITTEE.—

(1) IN GENERAL.—There shall be established a Trauma Research Interagency Coordinating Committee (in this section referred to as the “Coordinating Committee”).

(2) DUTIES.—The Coordinating Committee shall make recommendations regarding—

(A) the activities of the Program to be carried out by each of the agencies represented on the Committee and the amount of funds needed by each of the agencies for such activities; and

(B) effective collaboration among the agencies in carrying out the activities.

(3) COMPOSITION.—The Coordinating Committee shall be composed of the Directors of each of the agencies that, under subsection (c), have responsibilities under the Program, and any other individuals who are practitioners in the trauma field as designated by the Director of the National Institutes of Health.

(h) DEFINITIONS.—For purposes of this section:

(1) The term "designated trauma center" has the meaning given such term in section 1231(1).

(2) The term "Director" means the Director of the National Institutes of Health.

(3) The term "trauma" means any serious injury that could result in loss of life or in significant disability and that would meet pre-hospital triage criteria for transport to a designated trauma center.

TITLE XIII—HEALTH MAINTENANCE ORGANIZATIONS

REQUIREMENTS FOR HEALTH MAINTENANCE ORGANIZATIONS

SEC. 1301. [300e] (a) For purposes of this title, the term "health maintenance organization" means a public or private entity which is organized under the laws of any State and which (1) provides basic and supplemental health services to its members in the manner prescribed by subsection (b), and (2) is organized and operated in the manner prescribed by subsection (c).

(b) A health maintenance organization shall provide, without limitations as to time or cost other than those prescribed by or under this title, basic and supplemental health services to its members in the following manner:

(1) Each member is to be provided basic health services for a basic health services payment which (A) is to be paid on a periodic basis without regard to the dates health services (within the basic health services) are provided; (B) is fixed without regard to the frequency, extent, or kind of health service (within the basic health services) actually furnished; (C) except in the case of basic health services provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education, is fixed under a community rating system; and (D) may be supplemented by additional nominal payments which may be required for the provision of specific services (within the basic health services), except that such payments may not be required where or in such a manner that they serve (as determined under regulations of the Secretary) as a barrier to the delivery of health services. Such additional nominal payments shall be fixed in accordance with the regulations of the Secretary. If a health maintenance organization offers to its members the opportunity to obtain basic health services through a physician not described in subsection (b)(3)(A), the organization may require, in addition to payments described in clause (D) of this paragraph, a reasonable deductible to be paid by a member when obtaining a basic health service from such a physician. A health maintenance organization may include a health service, defined as a supplemental health service by section 1302(2), in the basic health services provided its members for a basic health services payment described in the first sentence. In the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 1310(d)) provided comprehensive health services on a prepaid basis, the requirement of clause (C) shall not apply to such entity until the expiration of the forty-eight month period beginning with the month following the month in which the entity became such a qualified health organization. The requirements of this paragraph re-

specting the basic health services payment shall not apply to the provision of basic health services to a member for an illness or injury for which the member is entitled to benefits under a workmen's compensation law or an insurance policy but only to the extent such benefits apply to such services. For the provision of such services for an illness or injury for which a member is entitled to benefits under such a law, the health maintenance organization may, if authorized by such law, charge or authorize the provider of such services to charge, in accordance with the charges allowed under such law, the insurance carrier, employer, or other entity which under such law is to pay for the provision of such services or, to the extent that such member has been paid under such law for such services, such member. For the provision of such services for an illness or injury for which a member is entitled to benefits under an insurance policy, a health maintenance organization may charge or authorize the provider of such services to charge the insurance carrier under such policy or, to the extent that such member has been paid under such policy for such services, such member.

(2) For such payment or payments (hereinafter in this title referred to as "supplemental health services payments") as the health maintenance organization may require in addition to the basic health services payment, the organization may provide to each of its members any of the health services which are included in supplemental health services (as defined in section 1302(2)). Supplemental health services payments which are fixed on a prepayment basis shall be fixed under a community rating system unless the supplemental health services payment is for a supplemental health service provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education, except that, in the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 1310(d)) provided comprehensive health services on a prepaid basis, the requirement of this sentence shall not apply to such entity during the forty-eight month period beginning with the month following the month in which the entity became such a qualified health maintenance organization.

(3)(A) Except as provided in subparagraph (B), at least 90 percent of the services of a physician which are provided as basic health services shall be provided through—

(i) members of the staff of the health maintenance organization,

(ii) a medical group (or groups),

(iii) an individual practice association (or associations),

(iv) physicians or other health professionals who have contracted with the health maintenance organization for the provision of such services, or

(v) any combination of such staff, medical group (or groups), individual practice association (or associations) or physicians or other health professionals under contract with the organization.

(B) Subparagraph (A) does not apply to the provision of the services of a physician—

(i) which the health maintenance organization determines, in conformity with regulations of the Secretary, are unusual or infrequently used, or

(ii) which are provided a member of the organization in a manner other than that prescribed by subparagraph (A) because of an emergency which made it medically necessary that the service be provided to the member before it could be provided in a manner prescribed by subparagraph (A).

(C) Contracts between a health maintenance organization and health professionals for the provision of basic and supplemental health services shall include such provisions as the Secretary may require (including provisions requiring appropriate continuing education).

(D) Contracts between a health maintenance organization and health professionals for the provision of basic and supplemental health services shall include such provisions as the Secretary may require, but only to the extent that such requirements are designed to insure the delivery of quality health care services and sound fiscal management.

(4) Basic health services (and only such supplemental health services as members have contracted for) shall within the area served by the health maintenance organization be available and accessible to each of its members with reasonable promptness and in a manner which assures continuity, and when medically necessary be available and accessible twenty-four hours a day and seven days a week, except that a health maintenance organization which has a service area located wholly in a nonmetropolitan area may make a basic health service available outside its service area if that basic health service is not a primary care or emergency health care service and if there is an insufficient number of providers of that basic health service within the service area who will provide such service to members of the health maintenance organization. A member of a health maintenance organization shall be reimbursed by the organization for his expenses in securing basic and supplemental health services other than through the organization if the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition.

(5) To the extent that a natural disaster, war, riot, civil insurrection, or any other similar event not within the control of a health maintenance organization (as determined under regulations of the Secretary) results in the facilities, personnel, or financial resources of a health maintenance organization not being available to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of paragraphs (1) through (4) of this subsection, such requirements only require the organization to make a good-faith effort to provide or arrange for the provision of such service within such limitation on its facilities, personnel, or resources.

(c) Each health maintenance organization shall—

(1)(A) have—

(i) a fiscally sound operation, and

(ii) adequate provision against the risk of insolvency, which is satisfactory to the Secretary, and (B) have administrative and managerial arrangements satisfactory to the Secretary;

(2) assume full financial risk on a prospective basis for the provision of basic health services, except that a health maintenance organization may (A) obtain insurance or make other arrangements for the cost of providing to any member basic health services the aggregate value of which exceeds \$5,000 in any year, (B) obtain insurance or make other arrangements for the cost of basic health services provided to its members other than through the organization because medical necessity required their provision before they could be secured through the organization, (C) obtain insurance or make other arrangements for not more than 90 per centum of the amount by which its costs for any of its fiscal years exceed 115 per centum of its income for such fiscal year, and (D) make arrangements with physicians or other health professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions;

(3)(A) enroll persons who are broadly representative of the various age, social, and income groups within the area it serves, except that in the case of a health maintenance organization which has a medically underserved population located (in whole or in part) in the area it serves, not more than 75 per centum of the members of that organization may be enrolled from the medically underserved population unless the area in which such population resides is also a rural area (as designated by the Secretary), and (B) carry out enrollment of members who are entitled to medical assistance under a State plan approved under title XIX of the Social Security Act in accordance with procedures approved under regulations promulgated by the Secretary;

(4) not expel or refuse to re-enroll any member because of his health status or his requirements for health services;

(5) be organized in such a manner that provides meaningful procedures for hearing and resolving grievances between the health maintenance organization (including the medical group or groups and other health delivery entities providing health services for the organization) and the members of the organization;

(6) have organizational arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for its health services which program (A) stresses health outcomes, and (B) provides review by physicians and other health professionals of the process followed in the provision of health services;

(7) adopt at least one of the following arrangements to protect its members from incurring liability for payment of any fees which are the legal obligation of such organization—

(A) a contractual arrangement with any hospital that is regularly used by the members of such organization prohibiting such hospital from holding any such member liable for payment of any fees which are the legal obligation of such organization;

(B) insolvency insurance, acceptable to the Secretary;

(C) adequate financial reserve, acceptable to the Secretary; and

(D) other arrangements, acceptable to the Secretary, to protect members,

except that the requirements of this paragraph shall not apply to a health maintenance organization if applicable State law provides the members of such organization with protection from liability for payment of any fees which are the legal obligation of such organization; and

(8) provide, in accordance with regulations of the Secretary (including safeguards concerning the confidentiality of the doctor-patient relationship), an effective procedure for developing, compiling, evaluating, and reporting to the Secretary, statistics and other information (which the Secretary shall publish and disseminate on an annual basis and which the health maintenance organization shall disclose, in a manner acceptable to the Secretary, to its members and the general public) relating to (A) the cost of its operations, (B) the patterns of utilization of its services, (C) the availability, accessibility, and acceptability of its services, (D) to the extent practical, developments in the health status of its members, and (E) such other matters as the Secretary may require.

The Secretary shall issue regulations stating the circumstances under which the Secretary, in administering paragraph (1)(A), will consider the resources of an organization which owns or controls a health maintenance organization. Such regulations shall require as a condition to consideration of resources that an organization which owns or controls a health maintenance organization shall provide satisfactory assurances that it will assume the financial obligations of the health maintenance organization.¹

DEFINITIONS

SEC. 1302. [300e-1] For purposes of this title:

(1) The term "basic health services" means—

(A) physician services (including consultant and referral services by a physician);

(B) inpatient and outpatient hospital services;

(C) medically necessary emergency health services;

(D) short-term (not to exceed twenty visits), outpatient evaluative and crisis intervention mental health services;

¹Section 5(a)(3) of Public Law 100-517 provides that during the period prior to the effective date of regulations issued under section 1301(c) (above), the Secretary shall consider the application for qualification under section 1301(c)(1)(A) of certain health maintenance organizations that are owned or controlled by other organizations. This requirement to issue the regulations was established October 24, 1988 (the date of the enactment of Public Law 100-517).

(E) medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs;

(F) diagnostic laboratory and diagnostic and therapeutic radiologic services;

(G) home health services; and

(H) preventive health services (including (i) immunizations, (ii) well-child care from birth, (iii) periodic health evaluations for adults, (iv) voluntary family planning services, (v) infertility services, and (vi) children's eye and ear examinations conducted to determine the need for vision and hearing correction).

Such term does not include a health service which the Secretary, upon application of a health maintenance organization, determines is unusual and infrequently provided and not necessary for the protection of individual health. The Secretary shall publish in the Federal Register each determination made by him under the preceding sentence. If a service of a physician described in the preceding sentence may also be provided under applicable State law by a dentist, optometrist, podiatrist, psychologist, or other health care personnel a health maintenance organization may provide such service through a dentist, optometrist, podiatrist, psychologist, or other health care personnel (as the case may be) licensed to provide such service. Such term includes a health service directly associated with an organ transplant only if such organ transplant was required to be included in basic health services on April 15, 1985.¹ For purposes of this paragraph, the term "home health services" means health services provided at a member's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the health maintenance organization.

(2) The term "supplemental health services" means any health service which is not included as a basic health service under paragraph (1) of this section. If a health service provided by a physician may also be provided under applicable State law by a dentist, optometrist, podiatrist, psychologist, or other health care personnel, a health maintenance organization may provide such service through an optometrist, dentist, podiatrist, psychologist, or other health care personnel (as the case may be) licensed to provide such service.

(3) The term "member" when used in connection with a health maintenance organization means an individual who has entered into a contractual agreement, or on whose behalf a contractual arrangement has been entered into, with the organization under which the organization assumes the responsibility for the provision to such individual of basic health services and of such supplemental health services as may be contracted for.

¹This sentence was added by subsection (a) of section 812 of Public Law 99-660. Paragraph (1) of subsection (b) of such section provided that the sentence "shall take effect on October 1, 1985, and shall cease to be in effect on April 1, 1988." Paragraph (2) of such subsection provided as follows:

"(2) After April 1, 1988, for purposes of title XIII of the Public Health Service Act, no health service directly associated with an organ transplant shall be considered to be a basic health service if such service would otherwise have been added as a basic health service between April 15, 1985, and April 1, 1988."

(4) The term "medical group" means a partnership, association, or other group—

(A) which is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, podiatrists, and psychologists) as are necessary for the provision of health services for which the group is responsible;

(B) a majority of the members of which are licensed to practice medicine or osteopathy; and

(C) the members of which (i) as their principal professional activity engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility for the delivery of health services to members of a health maintenance organization, except that this clause does not apply before the end of the forty-eight month period beginning after the month in which the health maintenance organization¹ becomes a qualified health maintenance organization as defined in section 1310(d), or as authorized by the Secretary in accordance with regulations that take into consideration the usual circumstances of the group; (ii) pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services; (iii) share medical and other records and substantial portions of major equipment and of professional, technical, and administrative staff; (iv) arrange for and encourage continuing education in the field of clinical medicine and related areas for the members of the group; and (v) establish an arrangement whereby a member's enrollment status is not known to the health professional who provides health services to the member.

(5) The term "individual practice association" means a partnership, corporation, association, or other legal entity which has entered into a services arrangement (or arrangements) with persons who are licensed to practice medicine, osteopathy, dentistry, podiatry, optometry, psychology, or other health profession in a State and a majority of whom are licensed to practice medicine or osteopathy. Such an arrangement shall provide—

(A) that such persons shall provide their professional services in accordance with a compensation arrangement established by the entity; and

(B) to the extent feasible, for the sharing by such persons of medical and other records, equipment, and professional, technical, and administrative staff.

(6) The term "health systems agency" means an entity which is designated in accordance with section 1515 of this Act.

(7) The term "medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services. Such a designation may be made by the Secretary only after consideration of the comments (if any) of (A) each State

¹ So in original. Probably should be "organization".

health planning and development agency which covers (in whole or in part) such urban or rural area or the area in which such population group resides, and (B) each health systems agency designated for a health service area which covers (in whole or in part) such urban or rural area or the area in which such population group resides.

(8)(A) The term "community rating system" means the systems, described in subparagraphs (B) and (C), of fixing rates of payments for health services. A health maintenance organization may fix its rates of payments under the system described in subparagraph (B) or (C) or under both such systems, but a health maintenance organization may use only one such system for fixing its rates of payments for any one group.

(B) A system of fixing rates of payment for health services may provide that the rates shall be fixed on a per-person or per-family basis and may authorize the rates to vary with the number of persons in a family, but, except as authorized in subparagraph (D), such rates must be equivalent for all individuals and for all families of similar composition.

(C) A system of fixing rates of payment for health services may provide that the rates shall be fixed for individuals and families by groups. Except as authorized in subparagraph (D), such rates must be equivalent for all individuals in the same group and for all families of similar composition in the same group. If a health maintenance organization is to fix rates of payment for individuals and families by groups, it shall—

(i)(I) classify all of the members of the organization into classes based on factors which the health maintenance organization determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by the Secretary,

(II) determine its revenue requirements for providing services to the members of each class established under subclause (I), and

(III) fix the rates of payments for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under subclause (II) for providing services to them as members of the classes established under subclause (I), or

(ii) fix the rates of payments for the individuals and families of a group on the basis of the organization's revenue requirements for providing services to the group, except that the rates of payments for the individuals and families of a group of less than 100 persons may not be fixed at rates greater than 110 percent of the rate that would be fixed for such individuals and families under subparagraph (B) or clause (i) of this subparagraph.

The Secretary shall review the factors used by each health maintenance organization to establish classes under clause (i). If the Secretary determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, the Secretary shall disapprove such factor for such purpose. If a health maintenance organization is to fix rates of payment for a

group under clause (ii), it shall, upon request of the entity with which it contracts to provide services to such group, disclose to that entity the method and data used in calculating the rates of payment.

(D) The following differentials in rates of payments may be established under the systems described in subparagraphs (B) and (C):

(i) Nominal differentials in such rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of members:

(I) Individual members (including their families).

(II) Small groups of members (as determined under regulations of the Secretary).

(III) Large groups of members (as determined under regulations of the Secretary).

(ii) Nominal differentials in such rates may be established to reflect the compositing of the rates of payment in a systematic manner to accommodate group purchasing practices of the various employers.

(iii) Differentials in such rates may be established for members enrolled in a health maintenance organization pursuant to a contract with a governmental authority under section 1079 or 1086 of title 10, United States Code, or under any other governmental program (other than the health benefits program authorized by chapter 89 of title 5, United States Code) or any health benefits program for employees of States, political subdivision of States, and other public entities.

(9) The term "non-metropolitan area" means an area no part of which is within an area designated as a standard metropolitan statistical area by the Office of Management and Budget and which does not contain a city whose population exceeds fifty thousand individuals.

LOANS AND LOAN GUARANTEES FOR INITIAL COSTS OF OPERATION

SEC. 1305. [300e-4] (a) The Secretary may—

(1) make loans to public or private health maintenance organizations to assist them in meeting the amount by which their costs of operation during a period not to exceed the first sixty months of their operation exceed their revenues in that period;

(2) make loans to public or private health maintenance organizations to assist them in meeting the amount by which their costs of operation, which the Secretary determines are attributable to significant expansion in their membership or area served and which are incurred during a period not to exceed the first sixty months of their operation after such expansion, exceed their revenues in that period which the Secretary determines are attributable to such expansion; and

(3) guarantee to non-Federal lenders payment of the principal of and the interest on loans made to private health maintenance organizations for the amounts referred to in paragraphs (1) and (2).

No loan or loan guarantee may be made under this subsection for the costs of operation of a health maintenance organization unless the Secretary determines that the organization has made all reasonable attempts to meet such costs, and unless the Secretary has made a grant or loan to, entered into a contract with, or guaranteed a loan for, the organization in fiscal year 1981, 1982, 1983, 1984, or 1985 under this section or section 1304(b) (as in effect before October 1, 1985).

(b)(1) Except as provided in paragraph (2), the aggregate amount of principal of loans made or guaranteed, or both, under subsection (a) for a health maintenance organization may not exceed \$7,000,000. In any twelve-month period the amount disbursed to a health maintenance organization under this section (either directly by the Secretary, by an escrow agent under the terms of an escrow agreement, or by a lender under a guaranteed loan) may not exceed \$3,000,000.

(2) The cumulative total of the principal of the loans outstanding at any time which have been directly made or with respect to which guarantees have been issued under subsection (a) may not exceed such limitations as may be specified in appropriation Acts.

(c) Loans under this section shall be made from the fund established under section 1308(e).

(d) No loan may be made or guaranteed under this section after September 30, 1986.

(e) Of the sums used for loans under this section in any fiscal year from the loan fund established under section 1308(e), not less than 20 per centum shall be used for loans for projects (1) for the initial operation of health maintenance organizations which the Secretary determines have not less than 66 per centum of their membership drawn from residents of nonmetropolitan areas, and (2) the applications for which meet the requirements of this title for approval.

(f) In considering applications for loan guarantees under this section, the Secretary shall give special consideration to applications for health maintenance organizations which will serve medically underserved populations.

APPLICATION REQUIREMENTS

SEC. 1306. [300e-5] (a) No loan or loan guarantee may be made under this title unless an application therefor has been submitted to and approved by the Secretary.

(b) The Secretary may not approve an application for a loan or loan guarantee under this title unless—

(1) such application meets the requirements of section 1308;

(2) in the case of an application for assistance under section 1305, he determines that the applicant making the application would not be able to complete the project or undertaking for which the application is submitted without the assistance applied for;

(3) the application contains satisfactory specification of the existing or anticipated (A) population group or groups to be served by the proposed or existing health maintenance organi-

zation described in the application, (B) membership of such organization, (C) methods, terms, and periods of the enrollment of members of such organization, (D) estimated costs per member of the health and educational services to be provided by such organization and the nature of such costs, (E) sources of professional services for such organization, and organizational arrangements of such organization for providing health and educational services, (F) organizational arrangements of such organization for an ongoing quality assurance program in conformity with the requirements of section 1301(c), (G) sources of prepayment and other forms of payment for the services to be provided by such organization, (H) facilities, and additional capital investments and sources of financing therefor, available to such organization to provide the level and scope of services proposed, (I) administrative, managerial, and financial arrangements and capabilities of such organization, (J) role for members in the planning and policymaking for such organization, (K) grievance procedures for members of such organization, and (L) evaluations of the support for and acceptance of such organization by the population to be served, the sources of operating support, and the professional groups to be involved or affected thereby;

(4) contains or is supported by assurances satisfactory to the Secretary that the applicant making the application will, in accordance with such criteria as the Secretary shall by regulation prescribe, enroll, and maintain an enrollment of the maximum number of members that its available and potential resources (as determined under regulations of the Secretary) will enable it to effectively serve;

(5) in the case of an application made for a project which previously received a grant, contract, loan, or loan guarantee under this title, such application contains or is supported by assurances satisfactory to the Secretary that the applicant making the application has the financial capability to adequately carry out the purposes of such project and has developed and operated such project in accordance with the requirements of this title and with the plans contained in previous applications for such assistance;

(6) the application contains such assurances as the Secretary may require respecting the intent and the ability of the applicant to meet the requirements of paragraphs (1) and (2) of section 1301(b) respecting the fixing of basic health services payments and supplemental health services payments under a community rating system; and

(7) the application is submitted in such form and manner, and contains such additional information, as the Secretary shall prescribe in regulations.

An organization making multiple applications for more than one loan or loan guarantee under this title, simultaneously or over the course of time, shall not be required to submit duplicate or redundant information but shall be required to update the specifications (required by paragraph (3)) respecting the existing or proposed health maintenance organization in such manner and with such frequency as the Secretary may by regulation prescribe. In deter-

mining, for purposes of paragraph (2), whether an applicant would be able to complete a project or undertaking without the assistance applied for, the Secretary shall not consider any asset of the applicant the obligation of which for such undertaking or project would jeopardize the fiscal soundness of the applicant.

(c) The Secretary shall by regulation establish standards and procedures for health systems agencies to follow in reviewing and commenting on applications for loans and loan guarantees under this title.

ADMINISTRATION OF ASSISTANCE PROGRAMS

SEC. 1307. [300e-6] (a)(1) Each recipient of a loan or loan guarantee under this title shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of the loan (directly made or guaranteed), the total cost of the undertaking in connection with which the loan was given or used, the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary, or any of his duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients of a loan or loan guarantee under this title which relate to such assistance.

(b) Upon expiration of the period for which a loan or loan guarantee was provided an entity under this title, such entity shall make a full and complete report to the Secretary in such manner as he may by regulation prescribe. Each such report shall contain, among such other matters as the Secretary may by regulation require, descriptions of plans, developments, and operations relating to the matters referred to in section 1306(b)(3).

(d)¹ An entity which provides health services to a defined population on a prepaid basis and which has members who are entitled to insurance benefits under title XVIII of the Social Security Act or to medical assistance under a State plan approved under title XIX of such Act may be considered as a health maintenance organization for purposes of receiving assistance under this title if—

(1) with respect to its members who are entitled to such insurance benefits or to such medical assistance it (A) provides health services in accordance with section 1301(b), except that (i) it does not furnish to those members the health services (within the basic health services) for which it may not be compensated under such title XVIII or such State plan, and (ii) it does not fix the basic or supplemental health services payment for such members under a community rating system, and (B) is organized and operated in the manner prescribed by section 1301(c), except that it does not assume full financial risk on a prospective basis for the provision to such members of basic or supplemental health services with respect to which it is not required under such title XVIII or such State plan to assume such financial risk; and

¹ Former subsection (c) was repealed by section 803(a) of Public Law 99-660.

(2) with respect to its other members it provides health services in accordance with section 1301(b) and is organized and operated in the manner prescribed by section 1301(c).

An entity which provides health services to a defined population on a prepaid basis and which has members who are enrolled under the health benefits program authorized by chapter 89 of title 5, United States Code, may be considered as a health maintenance organization for purposes of receiving assistance under this title if with respect to its other members it provides health services in accordance with section 1301(b) and is organized and operated in the manner prescribed by section 1301(c).

GENERAL PROVISIONS RELATING TO LOAN GUARANTEES AND LOANS

SEC. 1308. [300e-7] (a)(1) The Secretary may not approve an application for a loan guarantee under this title unless he determines that (A) the terms, conditions, security (if any), and schedule and amount of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable, including a determination that the rate of interest does not exceed such per centum per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for loans with similar maturities, terms, conditions, and security and the risks assumed by the United States, and (B) the loan would not be available on reasonable terms and conditions without the guarantee under this title.

(2)(A) The United States shall be entitled to recover from the applicant for a loan guarantee under this title the amount of any payment made pursuant to such guarantee, unless the Secretary for good cause waives such right of recovery; and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

(B) To the extent permitted by subparagraph (C), any terms and conditions applicable to a loan guarantee under this title (including terms and conditions imposed under subparagraph (D)) may be modified by the Secretary to the extent he determines it to be consistent with the financial interest of the United States.

(C) Any loan guarantee made by the Secretary under this title shall be incontestable (i) in the hands of an applicant on whose behalf such guarantee is made unless the applicant engaged in fraud or misrepresentation in securing such guarantee, and (ii) as to any person (or his successor in interest) who makes or contracts to make a loan to such applicant in reliance thereon unless such person (or his successor in interest) engaged in fraud or misrepresentation in making or contracting to make such loan.

(D) guarantees of loans under this title shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this title will be achieved.

(b)(1) The Secretary may not approve an application for a loan under this title unless—

(A) the Secretary is reasonably satisfied that the applicant therefor will be able to make payments of principal and interest thereon when due, and

(B) the applicant provides the Secretary with reasonable assurances that there will be available to it such additional funds as may be necessary to complete the project or undertaking with respect to which such loan is requested.

(2) Any loan made under this title shall (A) have such security, (B) have such maturity date, (C) be repayable in such installments, (D) on the date the loan is made, bear interest at a rate comparable to the rate of interest prevailing on such date with respect to marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges, and (E) be subject to such other terms and conditions (including provisions for recovery in case of default), as the Secretary determines to be necessary to carry out the purposes of this title while adequately protecting the financial interests of the United States. On the date disbursements are made under a loan after the initial disbursement under the loan, the Secretary may change the rate of interest on the amount of the loan disbursed on that date to a rate which is comparable to the rate of interest prevailing on the date the subsequent disbursement is made with respect to marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

(3) The Secretary may, for good cause but with due regard to the financial interests of the United States, waive any right of recovery which he has by reason of the failure of a borrower to make payments of principal of and interest on a loan made under this title, except that if such loan is sold and guaranteed, any such waiver shall have no effect upon the Secretary's guarantee of timely payment of principal and interest.

(c)(1) The Secretary may from time to time, but with due regard to the financial interests of the United States, sell loans made by him under this title.

(2) The Secretary may agree, prior to his sale of any such loan, to guarantee to the purchaser (and any successor in interest of the purchaser) compliance by the borrower with the terms and conditions of such loan. Any such agreement shall contain such terms and conditions as the Secretary considers necessary to protect the financial interests of the United States or as otherwise appropriate. Any such agreement may (A) provide that the Secretary shall act as agent of any such purchaser for the purpose of collecting from the borrower to which such loan was made and paying over to such purchaser, any payments of principal and interest payable by such organization under such loan; and (B) provide for the repurchase by the Secretary of any such loan on such terms and conditions as may be specified in the agreement. The full faith and credit of the United States is pledged to the payment of all amounts which may be required to be paid under any guarantee under this paragraph.

(3) After any loan under this title to a public health maintenance organization has been sold and guaranteed under this subsection, interest paid on such loan which is received by the purchaser thereof (or his successor in interest) shall be included in the gross income of the purchaser of the loan (or his successor in inter-

est) for the purpose of chapter 1 of the Internal Revenue Code of 1954.

(4) Amounts received by the Secretary as proceeds from the sale of loans under this subsection shall be deposited in the loan fund established under subsection (e).

(5) Any reference in this title (other than in this subsection and in subsection (d)) to a loan guarantee under this title does not include a loan guarantee made under this subsection.

(d)(1) There is established in the Treasury a loan guarantee fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriation Acts, to enable him to discharge his responsibilities under loan guarantees issued by him under this title and to take the action authorized by subsection (f). There are authorized to be appropriated from time to time such amounts as may be necessary to provide the sums required for the fund. To the extent authorized in appropriation Acts, there shall also be deposited in the fund amounts received by the Secretary in connection with loan guarantees under this title and other property or assets derived by him from his operations respecting such loan guarantees, including any money derived from the sale of assets.

(2) If at any time the sums in the funds are insufficient to enable the Secretary to discharge his responsibilities under guarantees issued by him before October 1, 1986, under this title and to take the action authorized by subsection (f), he is authorized to issue to the Secretary of the Treasury notes or other obligations in such forms and denominations, bearing such maturities, and subject to such terms and conditions, as may be prescribed by the Secretary with the approval of the Secretary of Treasury. Such notes or other obligations shall bear interest at a rate determined by the Secretary of the Treasury, taking into consideration the current average market yield on outstanding marketable obligations of the United States of comparable maturities during the month preceding the issuance of the notes or other obligations. The Secretary of the Treasury shall purchase any notes and other obligations issued under this paragraph and for that purpose he may use as a public debt transaction the proceeds from the sale of any securities issued under the Second Liberty Bond Act, and the purposes for which the securities may be issued under that Act are extended to include any purchase of such notes and obligations. The Secretary of the Treasury may at any time sell any of the notes or other obligations acquired by him under this paragraph. All redemptions, purchases, and sales by the Secretary of the Treasury of such notes or other obligations shall be treated as public debt transactions of the United States. Sums borrowed under this paragraph shall be deposited in the fund and redemption of such notes and obligations shall be made by the Secretary from the fund.

(e) There is established in the Treasury a loan fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriation Acts, to enable him to make loans under this title and to take the action authorized by subsection (f). There shall also be deposited in

the fund amounts received by the Secretary as interest payments and repayment of principal on loans made under this title and other property or assets derived by him from his operations respecting such loans, from the sale of loans under subsection (c) of this section, or from the sale of assets.

(f) The Secretary may take such action as he deems appropriate to protect the interest of the United States in the event of a default on a loan made or guaranteed under this title, including taking possession of, holding, and using real property pledged as security for such a loan or loan guarantee.

AUTHORIZATIONS OF APPROPRIATIONS

SEC. 1309. [300e-8] (a) For grants under section 1317 there is authorized to be appropriated \$1,000,000 for each of the fiscal years 1982, 1983, and 1984.

(b) To meet the obligations of the loan fund established under section 1308(e) resulting from defaults on loans made from the fund and to meet the other obligations of the fund, there is authorized to be appropriated to the loan fund for fiscal years 1987, 1988, and 1989, such sums as may be necessary.

EMPLOYEES' HEALTH BENEFITS PLANS

SEC. 1310.¹ [300e-9] (a)(1) In accordance with regulations which the Secretary shall prescribe—

(A) each employer—

(i) which is now or hereafter required during any calendar quarter to pay its employees the minimum wage prescribed by section 6 of the Fair Labor Standards Act of 1938 (or would be required to pay its employees such wage but for section 13(a) of such Act), and

(ii) which during such calendar quarter employed an average number of employees of not less than 25, shall include in any health benefits plan, and

(B) any State and each political subdivision thereof which during any calendar quarter employed an average number of employees of not less than 25, as a condition of payment to the State of funds under section 314(d), 317, 318, 1002, 1525, or 1613, shall include in any health benefits plan, offered to such employees in the calendar year beginning after such calendar quarter the option of membership in qualified health maintenance organizations which are engaged in the provision of basic health services in health maintenance organization service areas in which at least 25 of such employees reside.

¹Effective 7 years after October 24, 1988, section 7(b) of Public Law 100-517 amends the text of section 1310 to read as provided in such section 7(b). The text of section 1310, as so amended, is provided in this compilation under the heading "Certain Provisions Relating to Health Maintenance Organizations".

Section 7(a)(3) of such Public Law provides that nothing in section 1310 shall be construed to supersede any provision of a collective bargaining agreement in effect on the date of enactment of such Act (October 24, 1988).

Section 9 of such Public Law provides as follows: "With respect to abortion services, the Secretary of Health and Human Services shall not promulgate or issue any regulations, policy statements, or interpretations or develop any practices concerning the performance of medically necessary procedures if such regulations, policy statements, interpretations, or practices would be inconsistent with those in effect on [October 24, 1988]."

(2) If any of the employees of an employer or State or political subdivision thereof described in paragraph (1) are represented by a collective bargaining representative or other employee representative designated or selected under any law, offer of membership in a qualified health maintenance organization required by paragraph (1) to be made in a health benefits plan offered to such employees (A) shall first be made to such collective bargaining representative or other employee representative, and (B) if such offer is accepted by such representative, shall then be made to each such employee.

(b) If there is more than one qualified health maintenance organization which is engaged in the provision of basic and supplemental health services in the area in which the employees of an employer or a State or political subdivision reside and if—

(1) one or more of such organizations provides more than one-half of its basic health services which are provided by physicians through physicians or other health professionals who are members of the staff of the organization or a medical group (or groups) and provides at least 90 percent of such services through physicians described in section 1301(b)(3)(A), and

(2) one or more of such organizations provides its basic health services which are provided by physicians through (A) an individual practice association (or associations), (B) individual physicians and other health professionals under contract with the organization, or (C) a combination of such association (or associations), medical group (or groups), staff, and individual physicians and other health professionals under contract with the organization and provides no more than 10 percent of such services through physicians who are not described in section 1301(b)(3)(A),

then of the qualified health maintenance organizations included in a health benefits plan of such employer or State or political subdivision pursuant to subsection (a) at least one shall be an organization which provides basic health services as described in clause (1) and at least one shall be an organization which provides basic health services as described in clause (2).

(c) No employer or State or political subdivision shall be required to pay more for health benefits as a result of the application of this section than would otherwise be required by any prevailing collective bargaining agreement or other legally enforceable contract for the provision of health benefits between the employer or State or political subdivision and its employees. Each employer or State or political subdivision which provides payroll deductions as a means of paying employees' contributions for health benefits or which provides a health benefits plan to which an employee contribution is not required and which is required by subsection (a) to offer his employees the option of membership in a qualified health maintenance organization shall, with the consent of an employee who exercises such option, arrange for the employee's contribution for such membership to be paid through payroll deductions. If a health benefits plan offered by an employer or a State or political subdivision under subsection (a) includes contributions for services offered under the plan, the employer or State or political subdivision shall make a contribution under the plan for services offered by a qualified health maintenance organization in an amount

which does not financially discriminate against an employee who enrolls in such organization. For purposes of the preceding sentence, an employer's or a State's or political subdivision's contribution does not financially discriminate if the employer's or State's or political subdivision's method of determining the contributions on behalf of all employees is reasonable and is designed to assure employees a fair choice among health benefits plans.

(d) For purposes of this section, the term "qualified health maintenance organization" means (1) a health maintenance organization which has provided assurances satisfactory to the Secretary that it provides basic and supplemental health services to its members in the manner prescribed by section 1301(b) and that it is organized and operated in the manner prescribed by section 1301(c), and (2) an entity which proposes to become a health maintenance organization and which the Secretary determines will when it becomes operational provide basic and supplemental health services to its members in the manner prescribed by section 1301(b) and will be organized and operated in the manner prescribed by section 1301(c).

(e)(1) Any employer who knowingly does not comply with one or more of the requirements of subsection (a), (b) or (c) shall be subject to a civil penalty of not more than \$10,000. If such non-compliance continues, a civil penalty may be assessed and collected under this subsection for each thirty-day period such noncompliance continues. Such penalty may be assessed by the Secretary and collected in a civil action brought by the United States in a United States district court.

(2) In any proceeding by the Secretary to assess a civil penalty under this subsection, no penalty shall be assessed until the employer charged shall have been given notice and an opportunity to present its views on such charge. In determining the amount of the penalty, or the amount agreed upon in compromise, the Secretary shall consider the gravity of the noncompliance and the demonstrated good faith of the employer charged in attempting to achieve rapid compliance after notification by the Secretary of a noncompliance.

(3) In any civil action brought to review the assessment of a civil penalty assessed under this subsection, the court shall, at the request of any party to such action, hold a trial de novo on the assessment of such civil penalty and in any civil action to collect such a civil penalty, the court shall, at the request of any party to such action, hold a trial de novo on the assessment of such civil penalty unless in a prior civil action to review the assessment of such penalty the court held a trial de novo on such assessment.

(f) For purposes of this section, the term "employer" does not include (1) the Government of the United States, the government of the District of Columbia or any territory or possession of the United States, a State or any political subdivision thereof, or any agency or instrumentality (including the United States Postal Service and Postal Rate Commission) of any of the foregoing, except that such term includes nonappropriated fund instrumentalities of the Government of the United States; or (2) a church, convention or association of churches, or any organization operated, supervised or controlled by a church, convention or association of churches

which organization (A) is an organization described in section 501(c)(3) of the Internal Revenue Code of 1954, and (B) does not discriminate (i) in the employment, compensation, promotion, or termination of employment of any personnel, or (ii) in the extension of staff or other privileges to any physician or other health personnel, because such persons seek to obtain or obtained health care, or participate in providing health care, through a health maintenance organization.

(g) If the Secretary, after reasonable notice and opportunity for hearing to a State, finds that it or any of its political subdivisions has failed to comply with one or more of the requirements of subsection (a), the Secretary shall terminate payments to such State under sections 314(d), 317, 318, 1002, 1525, and 1613 and notify the Governor of such State that further payments under such sections will not be made to the State until the Secretary is satisfied that there will no longer be any such failure to comply.

RESTRICTIVE STATE LAWS AND PRACTICES

SEC. 1311. [300e-10] (a) In the case of any entity—

(1) which cannot do business as a health maintenance organization in a State in which it proposes to furnish basic and supplemental health services because that State by law, regulation, or otherwise—

(A) requires as a condition to doing business in that State that a medical society approve the furnishing of services by the entity,

(B) requires that physicians constitute all or a percentage of its governing body,

(C) requires that all physicians or a percentage of physicians in the locale participate or be permitted to participate in the provision of services for the entity,

(D) requires that the entity meet requirements for insurers of health care services doing business in that State respecting initial capitalization and establishment of financial reserves against insolvency, or

(E) imposes requirements which would prohibit the entity from complying with the requirements of this title, and

(2) for which a grant, contract, loan, or loan guarantee was made under this title or which is a qualified health maintenance organization for purposes of section 1310 (relating to employees' health benefits plans),

such requirements shall not apply to that entity so as to prevent it from operating as a health maintenance organization in accordance with section 1301.

(b) No State may establish or enforce any law which prevents a health maintenance organization for which a grant, contract, loan, or loan guarantee was made under this title or which is a qualified health maintenance organization for purposes of section 1310 (relating to employees' health benefits plans), from soliciting members through advertising its services, charges, or other non-professional aspects of its operation. This subsection does not authorize any advertising which identifies, refers to, or makes any

qualitative judgment concerning, any health professional who provides services for a health maintenance organization.

(c) The Secretary shall, within 6 months after the date of the enactment of this subsection, develop a digest of State laws, regulations, and practices pertaining to development, establishment, and operation of health maintenance organizations which shall be updated at least annually and relevant sections of which shall be provided to the Governor of each State annually. Such digest shall indicate which State laws, regulations, and practices appear to be inconsistent with the operation of this section. The Secretary shall also insure that appropriate legal consultative assistance is available to the States for the purpose of complying with the provisions of this section.

CONTINUED REGULATION OF HEALTH MAINTENANCE ORGANIZATIONS

SEC. 1312. [300e-11] (a) If the Secretary determines that an entity which received a grant, contract, loan, or loan guarantee under this title as a health maintenance organization or which was included in a health benefits plan offered to employees pursuant to section 1310—

(1) fails to provide basic and supplemental services to its members,

(2) fails to provide such services in the manner prescribed by section 1301(b), or

(3) is not organized or operated in the manner prescribed by section 1301(c),

the Secretary may take the action authorized by subsection (b).

(b)(1) If the Secretary makes, with respect to any entity which provided assurances to the Secretary under section 1310(d)(1), a determination described in subsection (a), the Secretary shall notify the entity in writing of the determination. Such notice shall specify the manner in which the entity has not complied with such assurances and direct that the entity initiate (within 30 days of the date the notice is issued by the Secretary or within such longer period as the Secretary determines is reasonable) such action as may be necessary to bring (within such period as the Secretary shall prescribe) the entity into compliance with the assurances. If the entity fails to initiate corrective action within the period prescribed by the notice or fails to comply with the assurances within such period as the Secretary prescribes, then after the Secretary provides the entity a reasonable opportunity for reconsideration of his determination, including, at the entity's election, a fair hearing (A) the entity shall not be a qualified health maintenance organization for purposes of section 1310 until such date as the Secretary determines that it is in compliance with the assurances, and (B) each employer which has offered membership in the entity in compliance with section 1310, each lawfully recognized collective bargaining representative or other employee representative which represents the employees of each such employer, and the members of such entity shall be notified by the entity that the entity is not a qualified health maintenance organization for purposes of such section. The notice required by clause (B) of the preceding sentence shall contain, in readily understandable language, the reasons for the deter-

mination that the entity is not a qualified health maintenance organization. The Secretary shall publish in the Federal Register each determination referred to in this paragraph.

(2) If the Secretary makes, with respect to an entity which has received a grant, contract, loan, or loan guarantee under this title, a determination described in subsection (a), the Secretary may, in addition to any other remedies available to him, bring a civil action in the United States district court for the district in which such entity is located to enforce its compliance with the assurances it furnished respecting the provision of basic and supplemental health services or its organization or operation, as the case may be, which assurances were made in connection with its application under this title for the grant, contract, loan, or loan guarantee.

LIMITATION ON SOURCE OF FUNDING FOR HEALTH MAINTENANCE ORGANIZATIONS

SEC. 1313. [300e-12] No funds appropriated under any provision of this Act (except as provided in sections 329, 330, and 340) other than this title may be used—

(1) for grants or contracts for surveys or other activities to determine the feasibility of developing or expanding health maintenance organizations or other entities which provide, directly or indirectly, health services to a defined population on a prepaid basis;

(2) for grants or contracts, or for payments under loan guarantees, for planning projects for the establishment or expansion of such organizations or entities;

(3) for grants or contracts, or for payments under loan guarantees, for projects for the initial development or expansion of such organizations or entities; or

(4) for loans, or for payments under loan guarantees, to assist in meeting the costs of the initial operation after establishment or expansion of such organizations or entities or in meeting the costs of such organizations in acquiring or constructing ambulatory health care facilities.

ANNUAL REPORT

SEC. 1315. [300e-14] (a) The Secretary shall periodically review the programs of assistance authorized by this title and make an annual report to the Congress of a summary of the activities under each program. The Secretary shall include in such summary—

(1) a summary of each grant, contract, loan, or loan guarantee made under this title in the period covered by the report and a list of the health maintenance organizations which during such period became qualified health maintenance organizations for purposes of section 1310;

(2) the statistics and other information reported in such period to the Secretary in accordance with section 1301(c)(11);

(3) findings with respect to the ability of the health maintenance organizations assisted under this title—

(A) to operate on a fiscally sound basis without continued Federal financial assistance,

(B) to meet the requirements of section 1301(c) respecting their organization and operation,

(C) to provide basic and supplemental health services in the manner prescribed by section 1301(b),

(D) to include indigent and high-risk individuals in their membership, and

(E) to provide services to medically underserved populations; and

(4) findings with respect to—

(A) the operation of distinct categories of health maintenance organizations in comparison with each other,

(B) health maintenance organizations as a group in comparison with alternative forms of health care delivery, and

(C) the impact that health maintenance organizations, individually, by category, and as a group, have on the health of the public.

(b) The Office of Management and Budget may review the Secretary's report under subsection (a) before its submission to the Congress, but the Office may not revise the report or delay its submission, and it may submit to the Congress its comments (and those of other departments or agencies of the Government) respecting such report.

TRAINING AND TECHNICAL ASSISTANCE

SEC. 1317. [300e-16] (a)(1) The Secretary shall establish a National Health Maintenance Organization Intern Program (hereinafter in this subsection referred to as the "Program") for the purpose of providing training to individuals to become administrators and medical directors of health maintenance organizations or to assume other managerial positions with health maintenance organizations. Under the Program the Secretary may directly provide internships for such training and may make grants to or enter into contracts with health maintenance organizations and other entities to provide such internships.

(2) No internship may be provided by the Secretary and no grant may be made or contract entered into by the Secretary for the provision of internships unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be in such form and contain such information, and be submitted to the Secretary in such manner, as the Secretary shall prescribe. Section 1306 does not apply to an application submitted under this section.

(3) Internships under the Program shall provide for such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the recipients of the internships as the Secretary deems necessary. An internship provided an individual for training at a health maintenance organization or any other entity shall also provide for payments to be made to the organization or other entity for the cost of support services (including the cost of salaries, supplies, equipment, and related items) provided such individual by such organization or other entity. The amount of any such payments to any organization or other entity shall be

determined by the Secretary and shall bear a direct relationship to the reasonable costs of the organization or other entity for establishing and maintaining its training programs.

(4) Payments under grants under the Program may be made in advance or by way of reimbursement, and at such intervals and on such conditions, as the Secretary finds necessary.

(b) The Secretary shall provide technical assistance (1) to entities intending to become a qualified health maintenance organization within the meaning of section 1310(d), and (2) to health maintenance organizations. The Secretary may provide such technical assistance through grants to public and nonprofit private entities and contracts with public and private entities.

(c) The authority of the Secretary to enter into contracts under subsections (a) and (b) shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

FINANCIAL DISCLOSURE

SEC. 1318. [300e-17] (a) Each health maintenance organization shall, in accordance with regulations of the Secretary, report to the Secretary financial information which shall include the following:

(1) Such information as the Secretary may require demonstrating that the health maintenance organization has a financially sound operation.

(2) A copy of the report, if any, filed with the Health Care Financing Administration containing the information required to be reported under section 1124 of the Social Security Act by disclosing entities and the information required to be supplied under section 1902(a)(38) of such Act.

(3) A description of transactions, as specified by the Secretary, between the health maintenance organization and a party in interest. Such transactions shall include—

(A) any sale or exchange, or leasing of any property between the health maintenance organization and a party in interest;

(B) any furnishing for consideration of goods, services (including management services), or facilities between the health maintenance organization and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical group (or groups), individual practice association (or associations), or any combination thereof; and

(C) any lending of money or other extension of credit between a health maintenance organization and a party in interest.

The Secretary may require that information reported respecting a health maintenance organization which controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(b) For the purposes of this section the term "party in interest" means:

(1) any director, officer, partner, or employee responsible for management or administration of a health maintenance organization, any person who is directly or indirectly the beneficial owner of more than 5 per centum of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 per centum of the health maintenance organization, and, in the case of a health maintenance organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(2) any entity in which a person described in paragraph (1)—

(A) is an officer or director;

(B) is a partner (if such entity is organized as a partnership);

(C) has directly or indirectly a beneficial interest of more than 5 per centum of the equity; or

(D) has a mortgage, deed of trust, note, or other interest valuing more than 5 per centum of the assets of such entity;

(3) any person directly or indirectly controlling, controlled by, or under common control with a health maintenance organization; and

(4) any spouse, child, or parent of an individual described in paragraph (1).

(c) Each health maintenance organization shall make the information reported pursuant to subsection (a) available to its enrollees upon reasonable request.

(d) The Secretary shall, as he deems necessary, conduct an evaluation of transactions reported to the Secretary under subsection (a)(3) for the purpose of determining their adverse impact, if any, on the fiscal soundness and reasonableness of charges to the health maintenance organization with respect to which they transpired. The Secretary shall evaluate the reported transactions of not less than five, or if there are more than twenty health maintenance organizations reporting such transactions, not less than one-fourth of the health maintenance organizations reporting any such transactions under subsection (a)(3).

(f)¹ Nothing in this section shall be construed to confer upon the Secretary any authority to approve or disapprove the rates charged by any health maintenance organization.

(g) Any health maintenance organization failing to file with the Secretary the annual financial statement required in subsection (a) shall be ineligible for any Federal assistance under this title until such time as such statement is received by the Secretary and shall not be a qualified health maintenance organization for purposes of section 1310.

¹ Subsection (e) was repealed by section 810 of Public Law 99-660.

(h) Whoever knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any statement filed pursuant to this section shall be guilty of a felony and upon conviction thereof shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

TITLE XIV—SAFETY OF PUBLIC WATER SYSTEMS
[For Text of This Title See the Environmental Law
Compilation]

TITLE XV—PREVENTIVE HEALTH MEASURES WITH RESPECT TO BREAST AND CERVICAL CANCERS

SEC. 1501. [300k] ESTABLISHMENT OF PROGRAM OF GRANTS TO STATES.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States on the basis of an established competitive review process for the purpose of carrying out programs—

(1) to screen women for breast and cervical cancer as a preventive health measure;

(2) to provide appropriate referrals for medical treatment of women screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services;

(3) to develop and disseminate public information and education programs for the detection and control of breast and cervical cancer;

(4) to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of breast and cervical cancer;

(5) to establish mechanisms through which the States can monitor the quality of screening procedures for breast and cervical cancer, including the interpretation of such procedures; and

(6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate surveillance or program-monitoring activities.

(b) GRANT AND CONTRACT AUTHORITY OF STATES.—

(1) IN GENERAL.—A State receiving a grant under subsection (a) may, subject to paragraphs (2) and (3), expend the grant to carry out the purpose described in such subsection through grants to, and contracts with, public or nonprofit private entities.

(2) LIMITED AUTHORITY REGARDING OTHER ENTITIES.—In addition to the authority established in paragraph (1) for a State with respect to grants and contracts, the State may provide for screenings under subsection (a)(1) through entering into contracts with private entities that are not nonprofit entities.

(3) PAYMENTS FOR SCREENINGS.—The amount paid by a State to an entity under this subsection for a screening procedure under subsection (a)(1) may not exceed the amount that would be paid under part B of title XVIII of the Social Security

Act if payment were made under such part for furnishing the procedure to a woman enrolled under such part.

(c) SPECIAL CONSIDERATION FOR CERTAIN STATES.—In making grants under subsection (a) to States whose initial grants under such subsection are made for fiscal year 1995 or any subsequent fiscal year, the Secretary shall give special consideration to any State whose proposal for carrying out programs under such subsection—

(1) has been approved through a process of peer review; and

(2) is made with respect to geographic areas in which there is—

(A) a substantial rate of mortality from breast or cervical cancer; or

(B) a substantial incidence of either of such cancers.

(c)¹ COORDINATING COMMITTEE REGARDING YEAR 2000 HEALTH OBJECTIVES.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a committee to coordinate the activities of the agencies of the Public Health Service (and other appropriate Federal agencies) that are carried out toward achieving the objectives established by the Secretary for reductions in the rate of mortality from breast and cervical cancer in the United States by the year 2000. Such committee shall be comprised of Federal officers or employees designated by the heads of the agencies involved to serve on the committee as representatives of the agencies, and such representatives from other public or private entities as the Secretary determines to be appropriate.

SEC. 1502. [3001] REQUIREMENT OF MATCHING FUNDS.

(a) IN GENERAL.—The Secretary may not make a grant under section 1501 unless the State involved agrees, with respect to the costs to be incurred by the State in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under subsection (b)) toward such costs in an amount equal to not less than \$1 for each \$3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(b) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

(1) IN GENERAL.—Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(2) MAINTENANCE OF EFFORT.—In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the State involved toward the purpose de-

¹ There are two subsections (c) in the law. See Public Law 103-183, section 101(b) (107 Stat. 2227) and section 101(f) (107 Stat. 2228).

scribed in section 1501 for the 2-year period preceding the first fiscal year for which the State is applying to receive a grant under such section.

(3) **INCLUSION OF RELEVANT NON-FEDERAL CONTRIBUTIONS FOR MEDICAID.**—In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary shall, subject to paragraphs (1) and (2) of this subsection, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act by the State involved toward the purpose described in paragraphs (1) and (2) of section 1501(a).

SEC. 1502A. [3001-1] REQUIREMENT REGARDING MEDICAID.

The Secretary may not make a grant under section 1501 for a program in a State unless the State plan under title XIX of the Social Security Act for the State includes the screening procedures specified in subparagraphs (A) and (B) of section 1503(a)(2) as medical assistance provided under the plan.

SEC. 1503. [300m] REQUIREMENTS WITH RESPECT TO TYPE AND QUALITY OF SERVICES.

(a) **REQUIREMENT OF PROVISION OF ALL SERVICES BY DATE CERTAIN.**—The Secretary may not make a grant under section 1501 unless the State involved agrees—

(1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of section 1501(a), including making available screening procedures for both breast and cervical cancers;

(2) subject to subsection (b), to ensure that—

(A) in the case of breast cancer, both a physical examination of the breasts and the screening procedure known as a mammography are conducted; and

(B) in the case of cervical cancer, both a pelvic examination and the screening procedure known as a pap smear are conducted;

(3) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in section 1501(a) is provided; and

(4) to ensure that not more than 40 percent of the grant is expended to provide the services or activities described in paragraphs (3) through (6) of such section.

(b) **USE OF IMPROVED SCREENING PROCEDURES.**—The Secretary may not make a grant under section 1501 unless the State involved agrees that, if any screening procedure superior to a procedure described in subsection (a)(2) becomes commonly available and is recommended for use, any entity providing screening procedures pursuant to the grant will utilize the superior procedure rather than the procedure described in such subsection.

(c)¹ **QUALITY ASSURANCE REGARDING SCREENING PROCEDURES.**—The Secretary may not make a grant under section 1501

¹Section 101(c)(2) of Public Law 103-183 (107 Stat. 2228) provides as follows:

unless the State involved agrees that the State will, in accordance with applicable law, assure the quality of screening procedures conducted pursuant to such section.

SEC. 1504. [300n] ADDITIONAL REQUIRED AGREEMENTS.

(a) **PRIORITY FOR LOW-INCOME WOMEN.**—The Secretary may not make a grant under section 1501 unless the State involved agrees that low-income women will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of section 1501(a).

(b) **LIMITATION ON IMPOSITION OF FEES FOR SERVICES.**—The Secretary may not make a grant under section 1501 unless the State involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the woman involved; and

(3) will not be imposed on any woman with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(c) **STATEWIDE PROVISION OF SERVICES.**—

(1) **IN GENERAL.**—The Secretary may not make a grant under section 1501 unless the State involved agrees that services and activities under the grant will be made available throughout the State, including availability to members of any Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act).

(2) **WAIVER.**—The Secretary may waive the requirement established in paragraph (1) for a State if the Secretary determines that compliance by the State with the requirement would result in an inefficient allocation of resources with respect to carrying out the purpose described in section 1501(a).

(3) **GRANTS TO TRIBES AND TRIBAL ORGANIZATIONS.**—

(A) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to tribes and tribal organizations (as such terms are used in paragraph (1)) for the purpose of carrying out programs described in section 1501(a). This title applies to such a grant (in relation to the jurisdiction of the tribe or organization) to the same extent and in the same manner as such title applies to a grant to a State under section 1501 (in relation to the jurisdiction of the State).

(B) If a tribe or tribal organization is receiving a grant under subparagraph (A) and the State in which the tribe or organization is located is receiving a grant under sec-

“(2) **TRANSITION RULE REGARDING MAMMOGRAPHIES.**—With respect to the screening procedure for breast cancer known as a mammography, the requirements in effect on the day before the date of the enactment of this Act under section 1503(c) of the Public Health Service Act remain in effect (for an individual or facility conducting such procedures pursuant to a grant to a State under section 1501 of such Act) until there is in effect for the facility a certificate (or provisional certificate) issued under section 354 of such Act.”.

tion 1501, the requirement established in paragraph (1) for the State regarding the tribe or organization is deemed to have been waived under paragraph (2).

(d) **RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.**—The Secretary may not make a grant under section 1501 unless the State involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(e) **COORDINATION WITH OTHER BREAST AND CERVICAL CANCER PROGRAMS.**—The Secretary may not make a grant under section 1501 unless the State involved agrees that the services and activities funded through the grant shall be coordinated with other Federal, State, and local breast and cervical cancer programs.

(f) **LIMITATION ON ADMINISTRATIVE EXPENSES.**—The Secretary may not make a grant under section 1501 unless the State involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(g) **RESTRICTIONS ON USE OF GRANT.**—The Secretary may not make a grant under section 1501 unless the State involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.

(h) **RECORDS AND AUDITS.**—The Secretary may not make a grant under section 1501 unless the State involved agrees that—

(1) the State will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursement of, and accounting for, amounts received by the State under such section; and

(2) upon request, the State will provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller of the United States for purposes of auditing the expenditures by the State of the grant.

(i) **REPORTS TO SECRETARY.**—The Secretary may not make a grant under section 1501 unless the State involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

SEC. 1505. [300n-1] DESCRIPTION OF INTENDED USES OF GRANT.

The Secretary may not make a grant under section 1501 unless—

(1) the State involved submits to the Secretary a description of the purposes for which the State intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the State with a need for the services or activities described in section 1501(a);

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be co-

ordinated with any similar services or activities of public and nonprofit private entities; and

(4) the description provides assurances that the grant funds will be used in the most cost-effective manner.

SEC. 1506. [300n-2] REQUIREMENT OF SUBMISSION OF APPLICATION.

The Secretary may not make a grant under section 1501 unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in section 1505, and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this title.

SEC. 1507. [300n-3] TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) **TECHNICAL ASSISTANCE.**—The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to section 1501. The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.

(b) **PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.**—

(1) **IN GENERAL.**—Upon the request of a State receiving a grant under section 1501, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out such section and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) **CORRESPONDING REDUCTION IN PAYMENTS.**—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant under section 1501 to the State involved by an amount equal to the costs of detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 1508. [300n-4] EVALUATIONS AND REPORTS.

(a) **EVALUATIONS.**—The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to section 1501. Such evaluations shall include evaluations of the extent to which States carrying out such programs are in compliance with section 1501(a)(2) and with section 1504(c).

(b) **REPORT TO CONGRESS.**—The Secretary shall, not later than 1 year after the date on which amounts are first appropriated pursuant to section 1509(a), and annually thereafter, submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report summarizing evaluations carried out pursuant to subsection (a) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this title as the Secretary determines to be appropriate,

including recommendations regarding compliance by the States with section 1501(a)(2) and with section 1504(c).

SEC. 1509. [300n-4a] SUPPLEMENTAL GRANTS FOR ADDITIONAL PREVENTIVE HEALTH SERVICES.

(a) **DEMONSTRATION PROJECTS.**—In the case of States receiving grants under section 1501, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to not more than 3 such States to carry out demonstration projects for the purpose of—

(1) providing preventive health services in addition to the services authorized in such section, including screenings regarding blood pressure and cholesterol, and including health education;

(2) providing appropriate referrals for medical treatment of women receiving services pursuant to paragraph (1) and ensuring, to the extent practicable, the provision of appropriate follow-up services; and

(3) evaluating activities conducted under paragraphs (1) and (2) through appropriate surveillance or program-monitoring activities.

(b) **STATUS AS PARTICIPANT IN PROGRAM REGARDING BREAST AND CERVICAL CANCER.**—The Secretary may not make a grant under subsection (a) unless the State involved agrees that services under the grant will be provided only through entities that are screening women for breast or cervical cancer pursuant to a grant under section 1501.

(c) **APPLICABILITY OF PROVISIONS OF GENERAL PROGRAM.**—This title applies to a grant under subsection (a) to the same extent and in the same manner as such title applies to a grant under section 1501.

(d) **FUNDING.**—

(1) **IN GENERAL.**—Subject to paragraph (2), for the purpose of carrying out this section, there are authorized to be appropriated \$3,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.

(2) **LIMITATION REGARDING FUNDING WITH RESPECT TO BREAST AND CERVICAL CANCER.**—The authorization of appropriations established in paragraph (1) is not effective for a fiscal year unless the amount appropriated under section 1510(a) for the fiscal year is equal to or greater than \$100,000,000.

SEC. 1510. [300n-5] FUNDING FOR GENERAL PROGRAM.

(a) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this title, there are authorized to be appropriated \$50,000,000 for fiscal year 1991, such sums as may be necessary for each of the fiscal years 1992 and 1993, \$150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.

(b) **SET-ASIDE FOR TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES.**—Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out section 1507.

TITLE XVI—HEALTH RESOURCES DEVELOPMENT

PART A—LOANS AND LOAN GUARANTEES

AUTHORITY FOR LOANS AND LOAN GUARANTEES

SEC. 1601. [300q] (a)(1) The Secretary, during the period ending September 30, 1982, may, in accordance with this part, make loans from the fund established under section 1602(d) to any public or nonprofit private entity for projects for—

(A) the discontinuance of unneeded hospital services or facilities;

(B) the conversion of unneeded hospital services and facilities to needed health services and medical facilities, including outpatient medical facilities and facilities for long-term care;

(C) the renovation and modernization of medical facilities, particularly projects for the prevention or elimination of safety hazards, projects to avoid noncompliance with licensure or accreditation standards, or projects to replace obsolete facilities;

(D) the construction of new outpatient medical facilities; and

(E) the construction of new inpatient medical facilities in areas which have experienced (as determined by the Secretary) recent rapid population growth.

(2)(A) The Secretary, during the period ending September 30, 1982, may, in accordance with this part, guarantee to—

(i) non-Federal lenders for their loans to public and nonprofit private entities for medical facilities projects described in paragraph (1), and

(ii) the Federal Financing Bank for its loans to public and nonprofit private entities for such projects, payment of principal and interest on such loans.

(B) In the case of a guarantee of any loan to a public or nonprofit private entity under subparagraph (A)(i) which is located in an urban or rural poverty area, the Secretary may pay, to the holder of such loan and for and on behalf of the project for which the loan was made, amounts sufficient to reduce by not more than one-half the net effective interest rate otherwise payable on such loan if the Secretary finds that without such assistance the project could not be undertaken.

(b) The principal amount of a loan directly made or guaranteed under subsection (a) for a medical facilities project, when added to any other assistance provided such project under part B, may not exceed 90 per centum of the cost of such project unless the project is located in an area determined by the Secretary to be an urban or rural poverty area, in which case the principal amount, when added to other assistance under part B, may cover up to 100 per centum of such costs.

(c) The cumulative total of the principal of the loans outstanding at any time with respect to which guarantees have been issued, or which have been directly made, may not exceed such limitations as may be specified in appropriation Acts.

(d) The Secretary, with the consent of the Secretary of Housing and Urban Development, shall obtain from the Department of Housing and Urban Development such assistance with respect to the administration of this part as will promote efficiency and economy thereof.

GENERAL PROVISIONS RELATING TO LOAN GUARANTEES AND LOANS

SEC. 1602. [300q-2] (a)(1) The Secretary may not approve a loan guarantee for a project under this part unless he determines that (A) the terms, conditions, security (if any), and schedule and amount of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable, including a determination that the rate of interest does not exceed such per centum per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for similar loans and the risks assumed by the United States, and (B) the loan would not be available on reasonable terms and conditions without the guarantee under this part.

(2)(A) The United States shall be entitled to recover from the applicant for a loan guarantee under this part the amount of any payment made pursuant to such guarantee, unless the Secretary for good cause waives such right of recovery; and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

(B) To the extent permitted by subparagraph (C), any terms and conditions applicable to a loan guarantee under this part (including terms and conditions imposed under subparagraph (D)) may be modified by the Secretary to the extent he determines it to be consistent with the financial interest of the United States.

(C) Any loan guarantee made by the Secretary under this part shall be incontestable (i) in the hands of an applicant on whose behalf such guarantee is made unless the applicant engaged in fraud or misrepresentation in securing such guarantee, and (ii) as to any person (or his successor in interest) who makes or contracts to make a loan to such applicant in reliance thereon unless such person (or his successor in interest) engaged in fraud or misrepresentation in making or contracting to make such loan.

(D) Guarantees of loans under this part shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this title will be achieved.

(b)(1) The Secretary may not approve a loan under this part unless—

(A) the Secretary is reasonably satisfied that the applicant under the project for which the loan would be made will be able to make payments of principal and interest thereon when due, and

(B) the applicant provides the Secretary with reasonable assurances that there will be available to it such additional funds as may be necessary to complete the project or undertaking with respect to which such loan is requested.

(2) Any loan made under this part shall (A) have such security, (B) have such maturity date, (C) be repayable in such installments, (D) bear interest at a rate comparable to the current rate of interest prevailing, on the date the loan is made, with respect to loans guaranteed under this part, minus any interest subsidy made in accordance with section 1601(a)(2)(B) with respect to a loan made for a project located in an urban or rural poverty area, and (E) be subject to such other terms and conditions (including provisions for recovery in case of default), as the Secretary determines to be necessary to carry out the purposes of this title while adequately protecting the financial interests of the United States.

(3) The Secretary may, for good cause but with due regard to the financial interests of the United States, waive any right of recovery which he has by reasons of the failure of a borrower to make payments of principal of and interest on a loan made under this part, except that if such loan is sold and guaranteed, any such waiver shall have no effect upon the Secretary's guarantee of timely payment of principal and interest.

(c)(1) The Secretary shall from time to time, but with due regard to the financial interests of the United States, sell loans made under this part either on the private market or to the Federal National Mortgage Association in accordance with section 302 of the Federal National Mortgage Association Charter Act or to the Federal Financing Bank.

(2) Any loan so sold shall be sold for an amount which is equal (or approximately equal) to the amount of the unpaid principal of such loans as of time of sale.

(3)(A) The Secretary is authorized to enter into an agreement with the purchaser of any loan sold under this part under which the Secretary agrees—

(i) to guarantee to such purchaser (and any successor in interest to such purchaser) payments of the principal and interest payable under such loan, and

(ii) to pay as an interest subsidy to such purchaser (and any successor in interest of such purchaser) amounts which, when added to the amount of interest payable on such loan, are equivalent to a reasonable rate of interest on such loan as determined by the Secretary after taking into account the range of prevailing interest rates in the private market on similar loans and the risks assumed by the United States.

(B) Any agreement under subparagraph (A)—

(i) may provide that the Secretary shall act as agent of any such purchaser, for the purpose of collecting from the entity to which such loan was made and paying over to such purchaser any payments of principal and interest payable by such entity under such loan;

(ii) may provide for the repurchase by the Secretary of any such loan on such terms and conditions as may be specified in the agreement;

(iii) shall provide that, in the event of any default by the entity to which such loan was made in payment of principal or interest due on such loan, the Secretary shall, upon notification to the purchaser (or to the successor in interest of such purchaser), have the option to close out such loan (and any obligations of the Secretary with respect thereto) by paying to the purchaser (or his successor in interest) the total amount of outstanding principal and interest due thereon at the time of such notification; and

(iv) shall provide that, in the event such loan is closed out as provided in clause (iii), or in the event of any other loss incurred by the Secretary by reason of the failure of such entity to make payments of principal or interest on such loan, the Secretary shall be subrogated to all rights of such purchaser for recovery of such loss from such entity.

(4) Amounts received by the Secretary as proceeds from the sale of loans under this subsection shall be deposited in the fund established under subsection (d).

(5) If any loan to a public entity under this part is sold and guaranteed by the Secretary under this subsection, interest paid on such loan after its sale and any interest subsidy paid, under paragraph (3)(A)(ii), by the Secretary with respect to such loan which is received by the purchaser of the loan (or the purchaser's successor in interest) shall be included in the gross income of the purchaser or successor for the purpose of chapter 1 of the Internal Revenue Code of 1954.

(d)(1) There is established in the Treasury a loan and loan guarantee fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriation Acts—

(A) to enable him to make loans under this part,

(B) to enable him to discharge his responsibilities under loan guarantees issued by him under this part,

(C) for payment of interest under section 1601(a)(2)(B) on loans guaranteed under this part,

(D) for repurchase of loans under subsection (c)(3)(B),

(E) for payment of interest on loans which are sold and guaranteed, and

(F) to enable the Secretary to take the action authorized by subsection (f).

There are authorized to be appropriated from time to time such amounts as may be necessary to provide the sums required for the fund. There shall also be deposited in the fund amounts received by the Secretary in connection with loans and loan guarantees under this part and other property or assets derived by him from his operations respecting such loans and loan guarantees, including any money derived from the sale of assets.

(2) If at any time the sums in the funds are insufficient to enable the Secretary—

(A) to make payments of interest under section 1601(a)(2)(B),

(B) to otherwise comply with guarantees under this part of loans to nonprofit private entities,

(C) in the case of a loan which was made, sold, and guaranteed under this part, to make to the purchaser of such loan payments of principal and interest on such loan after default by the entity to which the loan was made, or

(D) to repurchase loans under subsection (c)(3)(B),

(E) to make payments of interest on loans which are sold and guaranteed, and

(F) to enable the Secretary to take the action authorized by subsection (f),

he is authorized to issue to the Secretary of the Treasury notes or other obligations in such forms and denominations bearing such maturities, and subject to such terms and conditions, as may be prescribed by the Secretary with the approval of the Secretary of the Treasury. Such notes or other obligations shall bear interest at a rate determined by the Secretary of the Treasury, taking into consideration the current average market yield on outstanding marketable obligations of the United States of comparable maturities during the month preceding the issuance of the notes or other obligations. The Secretary of the Treasury shall purchase any notes and other obligations issued under this paragraph and for that purpose he may use as a public debt transaction the proceeds from the sale of any securities issued under the Second Liberty Bond Act, and the purposes for which the securities may be issued under that Act are extended to include any purchase of such notes and obligations. The Secretary of the Treasury may at any time sell any of the notes or other obligations acquired by him under this paragraph. All redemptions, purchases, and sales by the Secretary of the Treasury of such notes or other obligations shall be treated as public debt transactions of the United States. Sums borrowed under this paragraph shall be deposited in the fund and redemption of such notes and obligations shall be made by the Secretary from the fund.

(e)(1) The assets, commitments, obligations, and outstanding balances of the loan guarantee and loan fund established in the Treasury by section 626 shall be transferred to the fund established by subsection (d) of this section.

(2) To provide additional capitalization for the fund established under subsection (d) there are authorized to be appropriated to the fund, such sums as may be necessary for the fiscal years ending June 30, 1975, June 30, 1976, September 30, 1977, September 30, 1978, September 30, 1979, September 30, 1980, September 30, 1981, and September 30, 1982.

(f)(1) The Secretary may take such action as may be necessary to prevent a default on a loan made or guaranteed under this part or under title VI, including the waiver of regulatory conditions, deferral of loan payments, renegotiation of loans, and the expenditure of funds for technical and consultative assistance, for the temporary payment of the interest and principal on such a loan, and for other purposes. Any such expenditure made under the preceding sentence on behalf of a medical facility shall be made under such terms and conditions as the Secretary shall prescribe, including the implementation of such organizational, operational, and financial reforms as the Secretary determines are appropriate and the disclosure of such financial or other information as the Sec-

retary may require to determine the extent of the implementation of such reforms.

(2) The Secretary may take such action, consistent with State law respecting foreclosure procedures, as he deems appropriate to protect the interest of the United States in the event of a default on a loan made or guaranteed under this part or under title VI, including selling real property pledged as security for such a loan or loan guarantee and for a reasonable period of time taking possession of, holding, and using real property pledged as security for such a loan or loan guarantee.

PART B—PROJECT GRANTS

PROJECT GRANTS

SEC. 1610. [300r] (a)(1)(A) The Secretary may make grants for construction or modernization projects designed to—

(i) eliminate or prevent in medical facilities imminent safety hazards as defined by Federal, State, or local fire, building, or life safety codes or regulations, or

(ii) avoid noncompliance by medical facilities with State or voluntary licensure or accreditation standards.

(B) A grant under subparagraph (A) may only be made to—

(i) a State or political subdivision of a State, including any city, town, county, borough, hospital district authority, or public or quasi-public corporation, for any medical facility owned or operated by the State or political subdivision; and

(ii) a nonprofit private entity for any medical facility owned or operated by the entity but only if the Secretary determines—

(I) the level of community service provided by the facility and the proportion of its patients who are unable to pay for services rendered in the facility is similar to such level and proportion in a medical facility of a State or political subdivision, and

(II) that without a grant under subparagraph (A) there would be a disruption of the provision of health care to low-income individuals.

(2) The amount of any grant under paragraph (1) may not exceed 75 per centum of the cost of the project for which the grant is made unless the project is located in an area determined by the Secretary to be an urban or rural poverty area, in which case the grant may cover up to 100 per centum of such costs.

(3) There are authorized to be appropriated for grants under paragraph (1) \$40,000,000 for the fiscal year ending September 30, 1980, \$50,000,000 for the fiscal year ending September 30, 1981, and \$50,000,000 for the fiscal year ending September 30, 1982. Funds available for obligation under this subsection (as in effect before the date of the enactment of the Health Planning and Resources Development Amendments of 1979) in the fiscal year ending September 30, 1979, shall remain available for obligation under this subsection in the succeeding fiscal year.

(b)(1) The Secretary may make grants to public and nonprofit private entities for projects for (A) construction or modernization of outpatient medical facilities which are located apart from hospitals

and which will provide services for medically underserved populations, and (B) conversion of existing facilities into outpatient medical facilities or facilities for long-term care to provide services for such populations.

(2) The amount of any grant under paragraph (1) may not exceed 80 per centum of the cost of the project for which the grant is made unless the project is located in an area determined by the Secretary to be an urban or rural poverty area, in which case the grant may cover up to 100 per centum of such costs.

(3) There are authorized to be appropriated for grants under paragraph (1) \$15,000,000 for the fiscal year ending September 30, 1981, and \$15,000,000 for the fiscal year ending September 30, 1982.

PART C—GENERAL PROVISIONS

GENERAL REGULATIONS

SEC. 1620. [300s] The Secretary shall by regulation—

(1) prescribe the manner in which he shall determine the priority among projects for which assistance is available under part A or B, based on the relative need of different areas for such projects and giving special consideration—

(A) to projects for medical facilities serving areas with relatively small financial resources and for medical facilities serving rural communities,

(B) in the case of projects for modernization of medical facilities, to projects for facilities serving densely populated areas,

(C) in the case of projects for construction of outpatient medical facilities, to projects that will be located in, and provide services for residents of, areas determined by the Secretary to be rural or urban poverty areas,

(D) to projects designed to (i) eliminate or prevent imminent safety hazards as defined by Federal, State, or local fire, building, or life safety codes or regulations, or (ii) avoid noncompliance with State or voluntary licensure or accreditation standards, and

(E) to projects for medical facilities which, alone or in conjunction with other facilities, will provide comprehensive health care, including outpatient and preventive care as well as hospitalization;

(2) prescribe for medical facilities projects assisted under part A or B general standards of construction, modernization, and equipment, which standards may vary on the basis of the class of facilities and their location; and

(3) prescribe the general manner in which any entity which receives financial assistance under part A or B or has received financial assistance under part A or B or title VI shall be required to comply with the assurances required to be made at the time such assistance was received and the means by which such entity shall be required to demonstrate compliance with such assurances.

An entity subject to the requirements prescribed pursuant to paragraph (3) respecting compliance with assurances made in connec-

tion with receipt of financial assistance shall submit periodically to the Secretary data and information which reasonably supports the entity's compliance with such assurances. The Secretary may not waive the requirement of the preceding sentence.

APPLICATIONS

SEC. 1621. [300s-1] (a) No loan, loan guarantee, or grant may be made under part A or B for a medical facilities project unless an application for such project has been submitted to and approved by the Secretary. If two or more entities join in a project, an application for such project may be filed by any of such entities or by all of them.

(b)(1) An application for a medical facilities project shall be submitted in such form and manner as the Secretary shall by regulation prescribe and shall, except as provided in paragraph (2), set forth—

(A) in the case of a modernization project for a medical facility for continuation of existing health services, a finding by the State Agency of a continued need for such services, and, in the case of any other project for a medical facility, a finding by the State Agency of the need for the new health services to be provided through the medical facility upon completion of the project;

(B) in the case of an application for a grant, assurances satisfactory to the Secretary that (i) the applicant making the application would not be able to complete the project for which the application is submitted without the grant applied for, and (ii) in the case of a project to construct a new medical facility, it would be inappropriate to convert an existing medical facility to provide the services to be provided through the new medical facility;

(C) in the case of a project for the discontinuance of a service or facility or the conversion of a service or a facility, an evaluation of the impact of such discontinuance or conversion on the provision of health care in the health service area in which such service was provided or facility located;

(D) a description of the site of such project;

(E) plans and specifications therefor which meet the requirements of the regulations prescribed under section 1620(2);

(F) reasonable assurance that title to such site is or will be vested in one or more of the entities filing the application or in a public or other nonprofit entity which is to operate the facility on completion of the project;

(G) reasonable assurance that adequate financial support will be available for the completion of the project and for its maintenance and operation when completed, and, for the purpose of determining if the requirements of this subparagraph are met, Federal assistance provided directly to a medical facility which is located in an area determined by the Secretary to be an urban or rural poverty area or through benefits provided individuals served at such facility shall be considered as financial support;

(H) the type of assistance being sought under part A or B for the project;

(I) reasonable assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of work on a project will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Act of March 3, 1931 (40 U.S.C. 276a—276a-5, known as the Davis-Bacon Act), and the Secretary of Labor shall have with respect to such labor standards the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 FR 3176; 5 U.S.C. Appendix) and section 2 of the Act of June 13, 1934 (40 U.S.C. 276c);

(J) in the case of a project for the construction or modernization of an outpatient facility, reasonable assurance that the services of a general hospital will be available to patients at such facility who are in need of hospital care; and

(K) reasonable assurance that at all times after such application is approved (i) the facility or portion thereof to be constructed, modernized, or converted will be made available to all persons residing or employed in the area served by the facility, and (ii) there will be made available in the facility or portion thereof to be constructed, modernized, or converted a reasonable volume of services to persons unable to pay therefor and the Secretary, in determining the reasonableness of the volume of services provided, shall take into consideration the extent to which compliance is feasible from a financial viewpoint.

(2)(A) The Secretary may waive—

(i) the requirements of subparagraph (D) of paragraph (1) for compliance with modernization and equipment standards prescribed pursuant to section 1620(2), and

(ii) the requirement of subparagraph (E) of paragraph (1) respecting title to a project site,

in the case of an application for a project described in subparagraph (B) of this paragraph.

(B) A project referred to in subparagraph (A) is a project—

(i) for the modernization of an outpatient medical facility which will provide general purpose health services, which is not part of a hospital, and which will serve a medically underserved population as defined in section 1624 or as designated by a health systems agency, and

(ii) for which the applicant seeks a loan under part A the principal amount of which does not exceed \$20,000.

RECOVERY

SEC. 1622. [300s-1a] (a) If any facility with respect to which funds have been paid under this title shall, at any time within 20 years after the completion of construction or modernization—

(1) be sold or transferred to any entity (A) which is not qualified to file an application under section 1621 or 1642 or (B) which is not approved as a transferee by the State Agency of the State in which such facility is located, or its successor, or

(2) cease to be a public health center or a public or other nonprofit hospital, outpatient facility, facility for long-term care, or rehabilitation facility, the United States shall be entitled to recover, whether from the transferor or the transferee (or, in the case of a facility which has ceased to be public or nonprofit, from the owners thereof) an amount determined under subsection (c).

(b) The transferor of a facility which is sold or transferred as described in subsection (a)(1), or the owner of a facility the use of which is changed as described in subsection (a)(2), shall provide the Secretary written notice of such sale, transfer, or change not later than the expiration of 10 days from the date on which such sale, transfer, or change occurs.

(c)(1) Except as provided in paragraph (2), the amount the United States shall be entitled to recover under subsection (a) is an amount bearing the same ratio to the then value (as determined by the agreement of the parties or in an action brought in the district court of the United States for the district for which the facility involved is situated) of so much of the facility as constituted an approved project or projects as the amount of the Federal participation bore to the cost of the construction or modernization of such project or projects.

(2)(A) After the expiration of—

(i) 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b) in the case of a facility which is sold or transferred or the use of which changes after the date of the enactment of this subsection, or

(ii) thirty days after the date of enactment of this subsection or if later 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b), in the case of a facility which was sold or transferred or the use of which changed before the date of the enactment of this subsection,

the amount which the United States is entitled to recover under paragraph (1) with respect to a facility shall be the amount prescribed by paragraph (1) plus interest, during the period described in subparagraph (B), at a rate (determined by the Secretary) based on the average of the bond equivalent of the weekly 90-day Treasury bill auction rate.

(B) The period referred to in subparagraph (A) is the period beginning—

(i) in the case of a facility which was sold or transferred or the use of which changed before the date of the enactment of this subsection, thirty days after such date or if later 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b),

(ii) in the case of a facility with respect to which notice is provided in accordance with subsection (b), upon the expiration of 180 days after the receipt of such notice, or

(iii) in the case of a facility with respect to which such notice is not provided as prescribed by subsection (b), on the date of the sale, transfer, or changes of use for which such notice was to be provided,

and ending on the date the amount the United States is entitled to under paragraph (1) is collected.

(d)(1) The Secretary may waive the recovery rights of the United States under subsection (a)(1) with respect to a facility in any State if the Secretary determines, in accordance with regulations, that the entity to which the facility was sold or transferred—

(A) has established an irrevocable trust—

(i) in an amount equal to the greater of twice the cost of the remaining obligation of the facility under clause (ii) of section 1621(b)(1)(K) or the amount, determined under subsection (c), that the United States is entitled to recover, and

(ii) which will only be used by the entity to provide the care required by clause (ii) of section 1621(b)(1)(K); and

(B) will meet the obligation of the facility under clause (i) of section 1621(b)(1)(K).

(2) The Secretary may waive the recovery rights of the United States under subsection (a)(2) with respect to a facility in any State if the Secretary determines, in accordance with regulations, that there is good cause for waiving such rights with respect to such facility.

(e) The right of recovery of the United States under subsection (a) shall not constitute a lien on any facility with respect to which funds have been paid under this title.

CONTROL OF OPERATIONS

SEC. 1623. [300s-2] Except as otherwise specifically provided, nothing in this title shall be construed as conferring on any Federal officer, or employee the right to exercise any supervision or control over the administration, personnel, maintenance, or operation of any facility with respect to which any funds have been or may be expended under this title.

DEFINITIONS

SEC. 1624. [300s-3] Except as provided in section 1642(e), for purposes of this title—

(1) The term "hospital" includes general, tuberculosis, and other types of hospitals, and related facilities, such as laboratories, outpatient departments, nurses' home facilities, extended care facilities, facilities related to programs for home health services, self-care units, and central service facilities, operated in connection with hospitals, and also includes education or training facilities for health professional¹ personnel operated as an integral part of a hospital, but does not include any hospital furnishing primarily domiciliary care.

(2) The term "public health center" means a publicly owned facility for the provision of public health services, including related publicly owned facilities such as laboratories, clinics, and administrative offices operated in connection with such a facility.

¹So in original. Probably should be "professional".

(3) The term "nonprofit" as applied to any facility means a facility which is owned and operated by one or more non-profit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(4) The term "outpatient medical facility" means a medical facility (located in or apart from a hospital) for the diagnosis or diagnosis and treatment of ambulatory patients (including ambulatory inpatients)—

(A) which is operated in connection with a hospital;

(B) in which patient care is under the professional supervision of persons licensed to practice medicine or surgery in the State, or in the case of dental diagnosis or treatment, under the professional supervision of persons licensed to practice dentistry in the State; or

(C) which offers to patients not requiring hospitalization the services of licensed physicians in various medical specialties and which provides to its patients a reasonably full range of diagnostic and treatment services.

(5) The term "rehabilitation facility" means a facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of—

(A) medical evaluation and services, and

(B) psychological, social, or vocational evaluation and services,

under competent professional supervision, and in the case of which the major portion of the required evaluation and services is furnished within the facility; and either the facility is operated in connection with a hospital, or all medical and related health services are prescribed by, or are under the general direction of, persons licensed to practice medicine or surgery in the State.

(6) The term "facility for long-term care" means a facility (including a skilled nursing or intermediate care facility) providing in-patient care for convalescent or chronic disease patients who required skilled nursing or intermediate care and related medical services—

(A) which is a hospital (other than a hospital primarily for the care and treatment of mentally ill or tuberculosis patients) or is operated in connection with a hospital, or

(B) in which such care and medical services are prescribed by, or are performed under the general direction of, persons licensed to practice medicine or surgery in the State.

(7) The term "construction" means construction of new buildings and initial equipment of such buildings and, in any case in which it will help to provide a service not previously provided in the community, equipment of any buildings; including architects' fees, but excluding the cost of off-site improvements and, except with respect to public health centers, the cost of the acquisition of land

(8) The term "cost" as applied to construction modernization, or conversion means the amount found by the Secretary to be necessary for construction, modernization, or conversion,

respectively, under a project, except that, in the case of a modernization project or a project assisted under part D, such term does not include any amount found by the Secretary to be attributable to expansion of the bed capacity of any facility.

(9) The term "modernization" includes the alteration, expansion, major repair (to the extent permitted by regulations), remodeling, replacement, and renovation of existing buildings (including initial equipment thereof), and the replacement of obsolete equipment of existing buildings.

(10) The term "title,"¹ when used with reference to a site for a project, means a fee simple, or such other estate or interest (including a leasehold on which the rental does not exceed 4 per centum of the value of the land) as the Secretary finds sufficient to assure for a period of not less than twenty-five years' undisturbed use and possession for the purposes of construction, modernization, or conversion and operation of the project for a period of not less than (A) twenty years in the case of a project assisted under an allotment or grant under this title, or (B) the term of repayment of a loan made or guaranteed under this title in the case of a project assisted by a loan or loan guarantee.

(11) The term "medical facility" means a hospital, public health center, outpatient medical facility, rehabilitation facility, facility for long-term care, or other facility (as may be designated by the Secretary) for the provision of health care to ambulatory patients.

(12) The term "State Agency" means the State health planning and development agency of a State designated under title XV.

(13) The term "urban or rural poverty area" means an urban or rural geographical area (as defined by the Secretary) in which a percentage (as defined by the Secretary in accordance with the next sentence) of the residents of the area have incomes below the poverty level (as defined by the Secretary of Commerce). The percentage referred to in the preceding sentence shall be defined so that the percentage of the population of the United States residing in urban and rural poverty areas is—

(A) not more than the percentage of the total population of the United States with incomes below the poverty level (as so defined) plus five per centum, and

(B) not less than such percentage minus five per centum.

(14) The term "medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of health facilities or a population group designated by the Secretary as having a shortage of such facilities.

FINANCIAL STATEMENTS; RECORDS AND AUDIT

SEC. 1625. [300s-4] (a) In the case of any facility for which an allotment payment, grant, loan, or loan guarantee has been

¹ So in original. The comma probably should follow the ending quotations.

made under this title, the applicant for such payment, grant, loan, or loan guarantee (or, if appropriate, such other person as the Secretary may prescribe) shall file at least annually with the State Agency for the State in which the facility is located a statement which shall be in such form, and contain such information, as the Secretary may require to accurately show—

(1) the financial operations of the facility, and

(2) the costs to the facility of providing health services in the facility and the charges made by the facility for providing such services,

during the period with respect to which the statement is filed.

(b)(1) Each entity receiving Federal assistance under this title shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such entity of the proceeds of such assistance, the total cost of the project in connection with which such assistance is given or used, the amount of that portion of the cost of the project supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such entities which in the opinion of the Secretary or the Comptroller General may be related or pertinent to the assistance referred to in paragraph (1).

(c) Each such entity shall file at least annually with the Secretary a statement which shall be in such form, and contain such information, as the Secretary may require to accurately show—

(1) the financial operations of the facility constructed or modernized with such assistance, and

(2) the costs to such facility of providing health services in such facility, and the charges made for such services, during the period with respect to which the statement is filed.

TECHNICAL ASSISTANCE

SEC. 1626. [300s-5] The Secretary shall provide (either through the Department of Health, Education, and Welfare or by contract) all necessary technical and other nonfinancial assistance to any public or other entity which is eligible to apply for assistance under this title to assist such entity in developing applications to be submitted to the Secretary under section 1621 or 1642. The Secretary shall make every effort to inform eligible applicants of the availability of assistance under this title.

ENFORCEMENT OF ASSURANCES

SEC. 1627. [300s-6] The Secretary shall investigate and ascertain, on a periodic basis, with respect to each entity which is receiving financial assistance under this title or which has received financial assistance under title VI or this title, the extent of compliance by such entity with the assurances required to be made at the time such assistance was received. If the Secretary finds that such an entity has failed to comply with any such assurance, the Secretary shall report such noncompliance to the health systems agency for the health service area in which such entity is located and

the State health planning and development agency of the State in which the entity is located and shall take any action authorized by law (including an action for specific performance brought by the Attorney General upon request of the Secretary) which will effect compliance by the entity with such assurances. An action to effectuate compliance with any such assurance may be brought by a person other than the Secretary only if a complaint has been filed by such person with the Secretary and the Secretary has dismissed such complaint or the Attorney General has not brought a civil action for compliance with such assurance within six months after the date on which the complaint was filed with the Secretary.

PART D—AREA HEALTH SERVICES DEVELOPMENT FUNDS

DEVELOPMENT GRANTS FOR AREA HEALTH SERVICES DEVELOPMENT FUNDS

SEC. 1640. [300t] (a) The Secretary shall make in each fiscal year a grant to each health systems agency—

(1) with which there is in effect a designation agreement under section 1515(c),

(2) which has in effect an HSP and AIP reviewed by the Statewide Health Coordinating Council, and

(3) which, as determined under the review made under section 1535(c), is organized and operated in the manner prescribed by section 1512(b) and is performing its functions under section 1513 in a manner satisfactory to the Secretary, to enable the agency to establish and maintain an Area Health Services Development Fund from which it may make grants and enter into contracts in accordance with section 1513(c)(3).

(b)(1) Except as provided in paragraph (2), the amount of any grant under subsection (a) shall be determined by the Secretary after taking into consideration the population of the health service area for which the health systems agency is designated, the average family income of the area, and the supply of health services in the area.

(2) The amount of any grant under subsection (a) to a health systems agency for any fiscal year may not exceed the product of \$1 and the population of the health service area for which such agency is designated.

(c) No grant may be made under subsection (a) unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may require.

(d) For the purpose of making payments pursuant to grants under subsection (a), there are authorized to be appropriated \$25,000,000 for the fiscal year ending June 30, 1975, \$75,000,000 for the fiscal year ending June 30, 1976, \$120,000,000 each for the fiscal years ending September 30, 1977, and September 30, 1978, \$20,000,000 for the fiscal year ending September 30, 1981, and \$30,000,000 for the fiscal year ending September 30, 1982.

PART E—PROGRAM TO ASSIST AND ENCOURAGE THE VOLUNTARY DISCONTINUANCE OF UNNEEDED HOSPITAL SERVICES AND THE CONVERSION OF UNNEEDED HOSPITAL SERVICES TO OTHER HEALTH SERVICES NEEDED BY THE COMMUNITY

ESTABLISHMENT OF PROGRAM

SEC. 1641. [300t-11] The Secretary shall, by April 1, 1980, establish a program under which—

(1) grants and technical assistance may be provided to hospitals in operation on the date of the enactment of this part (A) for the discontinuance of unneeded hospital services, and (B) for the conversion of unneeded hospital services to other health services needed by the community; and

(2) grants may be provided to State Agencies designated under section 1521(b)(3) for reducing excesses in resources and facilities of hospitals.

GRANTS FOR DISCONTINUANCE AND CONVERSION

SEC. 1642. [300t-12] (a)(1) A grant to a hospital under the program shall be subject to such terms and conditions as the Secretary may by regulation prescribe to assure that the grant is used for the purpose for which it was made.

(2) The amount of any such grant shall be determined by the Secretary. The recipient of such a grant may use the grant—

(A) in the case of a grantee which discontinues the provision of all hospital services or all inpatient hospital services or an identifiable part of a hospital facility which provides inpatient hospital services, for the liquidation of the outstanding debt on the facilities of the grantee used for the provision of the services or for the liquidation of the outstanding debt of the grantee on such identifiable part;

(B) in the case of a grantee which is discontinuing the provision of an inpatient hospital service converts or proposes to convert an identifiable part of a hospital facility used in the provision of the discontinued service to the delivery of other health services, for the planning, development (including construction and acquisition of equipment), and delivery of the health service;

(C) to provide reasonable termination pay for personnel of the grantee who will lose employment because of the discontinuance of hospital services made by the grantee, retraining of such personnel, assisting such personnel in securing employment, and other costs of implementing arrangements described in subsection (c); and

(D) for such other costs which the Secretary determines may need to be incurred by the grantee in discontinuing hospital services.

(b)(1) No grant may be made to a hospital unless an application therefor is submitted to and approved by the Secretary. Such an application shall be in such form and submitted in such manner as the Secretary may prescribe and shall include—

(A) a description of each service to be discontinued and, if a part of a hospital is to be discontinued or converted to an-

other use in connection with such discontinuance, a description of such part;

(B) an evaluation of the impact of such discontinuance and conversion on the provision of health care in the health service area in which such service is provided;

(C) an estimate of the change in the applicant's costs which will result from such discontinuance and conversion; and

(D) reasonable assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of work on a project will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Act of March 3, 1931 (40 U.S.C. 276a—276a-5, known as the Davis-Bacon Act), and the Secretary of Labor shall have with respect to such labor standards the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 FR 3176; 5 U.S.C. Appendix) and section 2 of the Act of June 13, 1934 (40 U.S.C. 276c);

(E) such other information as the Secretary may require.

(2)(A) The health systems agency for the health service area in which is located a hospital applying for a grant under the program shall (i) in making the review of the applicant's application under section 1513(e), determine the need for each service or part proposed to be discontinued by the applicant, (ii) in the case of an application for the conversion of a facility, determine the need for each service which will be provided as a result of a conversion, and (iii) make a recommendation to the State Agency for the State in which the applicant is located respecting approval by the Secretary of the applicant's application.

(B) A State Agency which has received a recommendation from a health systems agency under subparagraph (A) respecting an application shall, after consideration of such recommendation, make a recommendation to the Secretary respecting the approval by the Secretary of the application. A State Agency's recommendation under this subparagraph respecting the approval of an application (i) shall be based upon (I) the need for each service or part proposed to be discontinued by the applicant, (II) in the case of an application for the conversion of a facility, the need for each service which will be provided as a result of the conversion, and (III) such other criteria as the Secretary may prescribe, and (ii) shall be accompanied by the health systems agency's recommendation made with respect to the approval of the application.

(C) In determining, under subparagraphs (A) and (B), the need for the service (or services) or part proposed to be discontinued or converted by an applicant for a grant, a health systems agency and State Agency shall give special consideration to the unmet needs and existing access patterns of urban or rural poverty populations.

(3)(A) The Secretary may not approve an application of a hospital for a grant—

(i) if a State Agency recommended that the application not be approved, or

(ii) if the Secretary is unable to determine that the cost of providing inpatient health services in the health service area in which the applicant is located will be less than if the inpa-

tient health services proposed to be discontinued were not discontinued.

(B) In considering applications of hospitals for grants the Secretary shall consider the recommendations of health systems agencies and State Agencies and shall give special consideration to applications (i) which will assist health systems agencies and State Agencies to meet the goals in their health systems plans and State health plans, or (ii) which will result in the greatest reduction in hospital costs within a health service area.

(c)(1) Except as provided in paragraph (3), the Secretary may not approve an application submitted under subsection (b) unless the Secretary of Labor has certified that fair and equitable arrangements have been made to protect the interests of employees affected by the discontinuance of services against a worsening of their positions with respect to their employment, including arrangements to preserve the rights of employees under collective-bargaining agreements, continuation of collective-bargaining rights consistent with the provisions of the National Labor Relations Act, reassignment of affected employees to other jobs, retraining programs, protecting pension, health benefits, and other fringe benefits of affected employees, and arranging adequate severance pay, if necessary.

(2) The Secretary of Labor shall by regulation prescribe guidelines for arrangements for the protection of the interests of employees affected by the discontinuance of hospital services. The Secretary of Labor shall consult with the Secretary of Health, Education, and Welfare in the promulgation of such guidelines. Such guidelines shall first be promulgated not later than the promulgation of regulations by the Secretary for the administration of the grants authorized by section 1641.

(3) The Secretary of Labor shall review each application submitted under subsection (b) to determine if the arrangements described in paragraph (1) have been made and if they are satisfactory and shall notify the Secretary respecting his determination. Such review shall be completed within—

(A) ninety days from the date of the receipt of the application from the Secretary of Health, Education, and Welfare, or

(B) one hundred and twenty days from such date if the Secretary of Labor has by regulation prescribed the circumstances under which the review will require at least one hundred and twenty days.

If within the applicable period, the Secretary of Labor does not notify the Secretary of Health, Education, and Welfare respecting his determination, the Secretary of Health, Education, and Welfare shall review the application to determine if the applicant has made the arrangements described in paragraph (1) and if such arrangements are satisfactory. The Secretary may not approve the application unless he determines that such arrangements have been made and that they are satisfactory.

(d) The records and audits requirements of section 705 shall apply with respect to grants made under subsection (a).

(e) For purposes of this part, the term "hospital" means, with respect to any fiscal year, an institution (including a distinct part

of an institution participating in the programs established under title XVIII of the Social Security Act)—

(1) which satisfies paragraphs (1) and (7) of section 1861(e) of such Act,

(2) imposes charges or accepts payments for services provided to patients, and

(3) the average duration of a patient's stay in which was thirty days or less in the preceding fiscal year,

but such term does not include a Federal hospital or a psychiatric hospital (as described in section 1861(f)(1) of the Social Security Act).

GRANTS TO STATES FOR REDUCTION OF EXCESS HOSPITAL CAPACITY

SEC. 1643. [300t-13] (a) For the purpose of demonstrating the effectiveness of various means for reducing excesses in resources and facilities of hospitals (referred to in this section as "excess hospital capacity"), the Secretary may make grants to State Agencies designated under section 1521(b)(3) to assist such Agencies in—

(1) identifying (by geographic region or by health service) excess hospital capacity,

(2) developing programs to inform the public of the costs associated with excess hospital capacity,

(3) developing programs to reduce excess hospital capacity in a manner which will produce the greatest savings in the cost of health care delivery,

(4) developing means to overcome barriers to the reduction of excess hospital capacity,

(5) in planning, evaluating, and carrying out programs to decertify health care facilities providing health services that are not appropriate, and

(6) any other activity related to the reduction of excess hospital capacity.

(b) Grants under subsection (a) shall be made on such terms and conditions as the Secretary may prescribe.

AUTHORIZATION OF APPROPRIATIONS

SEC. 1644. [300t-14] To make payments under grants under sections 1642 and 1643 there are authorized to be appropriated \$30,000,000 for the fiscal year ending September 30, 1980, \$50,000,000 for the fiscal year ending September 30, 1981, and \$75,000,000 for the fiscal year ending September 30, 1982, except that in any fiscal year not more than 10 percent of the amount appropriated under this section may be obligated for grants under section 1643.

TITLE XVII—HEALTH INFORMATION AND HEALTH PROMOTION

GENERAL AUTHORITY

SEC. 1701. [300u] (a) The Secretary shall—

(1) formulate national goals, and a strategy to achieve such goals, with respect to health information and health promotion, preventive health services, and education in the appropriate use of health care;

(2) analyze the necessary and available resources for implementing the goals and strategy formulated pursuant to paragraph (1), and recommend appropriate educational and quality assurance policies for the needed manpower resources identified by such analysis;

(3) undertake and support necessary activities and programs to—

(A) incorporate appropriate health education components into our society, especially into all aspects of education and health care,

(B) increase the application and use of health knowledge, skills, and practices by the general population in its patterns of daily living, and

(C) establish systematic processes for the exploration, development, demonstration, and evaluation of innovative health promotion concepts;

(4) undertake and support research and demonstrations respecting health information and health promotion, preventive health services, and education in the appropriate use of health care;

(5) undertake and support appropriate training in the operation of programs concerned with, health information and health promotion, preventive health services, and education in the appropriate use of health care;

(6) undertake and support, through improved planning and implementation of tested models and evaluation of results, effective and efficient programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care;

(7)(A) develop model programs through which employers in the public sector, and employers that are small businesses (as defined in section 3 of the Small Business Act), can provide for their employees a program to promote healthy behaviors and to discourage participation in unhealthy behaviors;

(B) provide technical assistance to public and private employers in implementing such programs (including private employers that are not small businesses and that will implement

programs other than the programs developed by the Secretary pursuant to subparagraph (A)); and

(C) in providing such technical assistance, give preference to small businesses;

(8) foster the exchange of information respecting, and foster cooperation in the conduct of, research, demonstration, and training programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care;

(9) provide technical assistance in the programs referred to in paragraph (8);

(10) use such other authorities for programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care as are available and coordinate such use with programs conducted under this title; and

(11) establish in the Office of the Assistant Secretary for Health an Office of Disease Prevention and Health Promotion, which shall—

(A) coordinate all activities within the Department which relate to disease prevention, health promotion, preventive health services, and health information and education with respect to the appropriate use of health care;

(B) coordinate such activities with similar activities in the private sector;

(C) establish a national information clearinghouse to facilitate the exchange of information concerning matters relating to health information and health promotion, preventive health services (which may include information concerning models and standards for insurance coverage of such services), and education in the appropriate use of health care, to facilitate access to such information, and to assist in the analysis of issues and problems relating to such matters; and

(D) support projects, conduct research, and disseminate information relating to preventive medicine, health promotion, and physical fitness and sports medicine.

The Secretary shall appoint a Director for the Office of Disease Prevention and Health Promotion established pursuant to paragraph (11) of this subsection. The Secretary shall administer this title in cooperation with health care providers, educators, voluntary organizations, businesses, and State and local health agencies in order to encourage the dissemination of health information and health promotion activities.

(b) For the purpose of carrying out this section and sections 1702 through 1705, there are authorized to be appropriated \$10,000,000 for fiscal year 1992, and such sums as may be necessary for each of the fiscal years 1993 through 1996.

(c) No grant may be made or contract entered into under this title unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may prescribe. Contracts may be entered into under this

title without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

RESEARCH PROGRAMS

SEC. 1702. [300u-1] (a) The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) research in health information and health promotion, preventive health services, and education in the appropriate use of health care. Applications for grants and contracts under this section shall be subject to appropriate peer review. The Secretary shall also—

(1) provide consultation and technical assistance to persons who need help in preparing research proposals or in actually conducting research;

(2) determine the best methods of disseminating information concerning personal health behavior, preventive health services and the appropriate use of health care and of affecting behavior so that such information is applied to maintain and improve health, and prevent disease, reduce its risk, or modify its course or severity;

(3) determine and study environmental, occupational, social, and behavioral factors which affect and determine health and ascertain those programs and areas for which educational and preventive measures could be implemented to improve health as it is affected by such factors;

(4) develop (A) methods by which the cost and effectiveness of activities respecting health information and health promotion, preventive health services, and education in the appropriate use of health care, can be measured, including methods for evaluating the effectiveness of various settings for such activities and the various types of persons engaged in such activities, (B) methods for reimbursement or payment for such activities, and (C) models and standards for the conduct of such activities, including models and standards for the education, by providers of institutional health services, of individuals receiving such services respecting the nature of the institutional health services provided the individuals and the symptoms, signs, or diagnoses which led to provision of such services;

(5) develop a method for assessing the cost and effectiveness of specific medical services and procedures under various conditions of use, including the assessment of the sensitivity and specificity of screening and diagnostic procedures; and

(6) enumerate and assess, using methods developed under paragraph (5), preventive health measures and services with respect to their cost and effectiveness under various conditions of use (which measures and services may include blood pressure screening, cholesterol screening and control, smoking cessation programs, substance abuse programs, cancer screening, dietary and nutritional counseling, diabetes screening and education, intraocular pressure screening, and stress management).

(b) The Secretary shall make a periodic survey of the needs, interest, attitudes, knowledge, and behavior of the American public regarding health and health care. The Secretary shall take into

consideration the findings of such surveys and the findings of similar surveys conducted by national and community health education organizations, and other organizations and agencies for formulating policy respecting health information and health promotion, preventive health services, and education in the appropriate use of health care.

COMMUNITY PROGRAMS

SEC. 1703. [300u-2] (a) The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) new and innovative programs in health information and health promotion, preventive health services, and education in the appropriate use of health care, and may specifically—

(1) support demonstration and training programs in such matters which programs (A) are in hospitals, ambulatory care settings, home care settings, schools, day care programs for children, and other appropriate settings representative of broad cross sections of the population, and include public education activities of voluntary health agencies, professional medical societies, and other private nonprofit health organizations, (B) focus on objectives that are measurable, and (C) emphasize the prevention or moderation of illness or accidents that appear controllable through individual knowledge and behavior;

(2) provide consultation and technical assistance to organizations that request help in planning, operating, or evaluating programs in such matters;

(3) develop health information and health promotion materials and teaching programs including (A) model curriculums for the training of educational and health professionals and paraprofessionals in health education by medical, dental, and nursing schools, schools of public health, and other institutions engaged in training of educational or health professionals, (B) model curriculums to be used in elementary and secondary schools and institutions of higher learning, (C) materials and programs for the continuing education of health professionals and paraprofessionals in the health education of their patients, (D) materials for public service use by the printed and broadcast media, and (E) materials and programs to assist providers of health care in providing health education to their patients; and

(4) support demonstration and evaluation programs for individual and group self-help programs designed to assist the participant in using his individual capacities to deal with health problems, including programs concerned with obesity, hypertension, and diabetes.

(b) The Secretary is authorized to make grants to States and other public and nonprofit entities to assist them in meeting the costs of demonstrating and evaluating programs which provide information respecting the costs and quality of health care or information respecting health insurance policies and prepaid health plans, or information respecting both. After the development of models pursuant to sections 1704(4) and 1704(5) for such information, no grant may be made under this subsection for a program

unless the information to be provided under the program is provided in accordance with one of such models applicable to the information.

(c) The Secretary is authorized to support by grant or contract (and to encourage others to support) private nonprofit entities working in health information and health promotion, preventive health services, and education in the appropriate use of health care. The amount of any grant or contract for a fiscal year beginning after September 30, 1978, for an entity may not exceed 25 per centum of the expenses of entity for such fiscal year for health information and health promotion, preventive health services, and education in the appropriate use of health care.

INFORMATION PROGRAMS

SEC. 1704. [300u-3] The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) such activities as may be required to make information respecting health information and health promotion, preventive health services, and education in the appropriate use of health care available to the consumers of medical care, providers of such care, schools, and others who are or should be informed respecting such matters. Such activities may include at least the following:

(1) The publication of information, pamphlets, and other reports which are specially suited to interest and instruct the health consumer, which information, pamphlets, and other reports shall be updated annually, shall pertain to the individual's ability to improve and safeguard his own health; shall include material, accompanied by suitable illustrations, on child care, family life and human development, disease prevention (particularly prevention of pulmonary disease, cardiovascular disease, and cancer), physical fitness, dental health, environmental health, nutrition, safety and accident prevention, drug abuse and alcoholism, mental health, management of chronic diseases (including diabetes and arthritis), and venereal diseases; and shall be designed to reach populations of different languages and of different social and economic backgrounds.

(2) Securing the cooperation of the communication media, providers of health care, schools, and others in activities designed to promote and encourage the use of health maintaining information and behavior.

(3) The study of health information and promotion in advertising and the making to concerned Federal agencies and others such recommendations respecting such advertising as are appropriate.

(4) The development of models and standards for the publication by States, insurance carriers, prepaid health plans, and others (except individual health practitioners) of information for use by the public respecting the cost and quality of health care, including information to enable the public to make comparisons of the cost and quality of health care.

(5) The development of models and standards for the publication by States, insurance carriers, prepaid health plans, and others of information for use by the public respecting health in-

surance policies and prepaid health plans, including information on the benefits provided by the various types of such policies and plans, the premium charges for such policies and plans, exclusions from coverage or eligibility for coverage, cost sharing requirements, and the ratio of the amounts paid as benefits to the amounts received as premiums and information to enable the public to make relevant comparisons of the costs and benefits of such policies and plans.

REPORT AND STUDY

SEC. 1705. [300u-4] (a) The Secretary shall, not later than two years after the date of the enactment of this title and annually thereafter, submit to the President for transmittal to Congress a report on the status of health information and health promotion, preventive health services, and education in the appropriate use of health care. Each such report shall include—

- (1) a statement of the activities carried out under this title since the last report and the extent to which each such activity achieves the purposes of this title;

- (2) an assessment of the manpower resources needed to carry out programs relating to health information and health promotion, preventive health services, and education in the appropriate use of health care, and a statement describing the activities currently being carried out under this title designed to prepare teachers and other manpower for such programs;

- (3) the goals and strategy formulated pursuant to section 1701(a)(1), the models and standards developed under this title, and the results of the study required by subsection (b) of this section; and

- (4) such recommendations as the Secretary considers appropriate for legislation respecting health information and health promotion, preventive health services, and education in the appropriate use of health care, including recommendations for revisions to and extension of this title.

(b) The Secretary shall conduct a study of health education services and preventive health services to determine the coverage of such services under public and private health insurance programs, including the extent and nature of such coverage and the cost sharing requirements required by such programs for coverage of such services.

CENTERS FOR RESEARCH AND DEMONSTRATION OF HEALTH PROMOTION AND DISEASE PREVENTION

SEC. 1706. [300u-5] (a) The Secretary shall make grants or enter into contracts with academic health centers for the establishment, maintenance, and operation of centers for research and demonstration with respect to health promotion and disease prevention. Centers established, maintained, or operated under this section shall undertake research and demonstration projects in health promotion, disease prevention, and improved methods of appraising health hazards and risk factors, and shall serve as demonstration sites for the use of new and innovative research in public health techniques to prevent chronic diseases.

(b) Each center established, maintained, or operated under this section shall—

(1) be located in an academic health center with—

(A) a multidisciplinary faculty with expertise in public health and which has working relationships with relevant groups in such fields as medicine, psychology, nursing, social work, education and business;

(B) graduate training programs relevant to disease prevention;

(C) a core faculty in epidemiology, biostatistics, social sciences, behavioral and environmental health sciences, and health administration;

(D) a demonstrated curriculum in disease prevention;

(E) a capability for residency training in public health or preventive medicine; and

(F) such other qualifications as the Secretary may prescribe;

(2) conduct—

(A) health promotion and disease prevention research, including retrospective studies and longitudinal prospective studies in population groups and communities;

(B) demonstration projects for the delivery of services relating to health promotion and disease prevention to defined population groups using, as appropriate, community outreach and organization techniques and other methods of educating and motivating communities; and

(C) evaluation studies on the efficacy of demonstration projects conducted under subparagraph (B) of this paragraph.

The design of any evaluation study conducted under subparagraph (C) shall be established prior to the commencement of the demonstration project under subparagraph (B) for which the evaluation will be conducted.

(c)(1) In making grants and entering into contracts under this section, the Secretary shall provide for an equitable geographical distribution of centers established, maintained, and operated under this section and for the distribution of such centers among areas containing a wide range of population groups which exhibit incidences of diseases which are most amenable to preventive intervention.

(2) The Secretary, through the Director of the Centers for Disease Control and Prevention and in consultation with the Director of the National Institutes of Health, shall establish procedures for the appropriate peer review of applications for grants and contracts under this section by peer review groups composed principally of non-Federal experts.

(d) For purposes of this section, the term “academic health center” means a school of medicine, a school of osteopathy, or a school of public health, as such terms are defined in section 701(4).

(e) For the purpose of carrying out this section, there are authorized to be appropriated \$10,000,000 for fiscal year 1992, and such sums as may be necessary for each of the fiscal years 1993 through 1998.

ESTABLISHMENT OF OFFICE OF MINORITY HEALTH

SEC. 1707. [300u-6] (a) IN GENERAL.—There is established an Office of Minority Health within the Office of the Assistant Secretary for Health. There shall be in the Department of Health and Human Services a Deputy Assistant Secretary for Minority Health, who shall be the head of the Office of Minority Health. The Secretary, acting through such Deputy Assistant Secretary, shall carry out this section.

(b) DUTIES.—The Secretary shall, with respect to the health concerns of individuals from disadvantaged backgrounds, including racial and ethnic minorities—

(1) establish short-range and long-range goals and objectives and coordinate all other activities within the Department of Health and Human Services that relate to disease prevention, health promotion, service delivery, and research concerning such individuals;

(2) enter into interagency agreements with other agencies of the Service to increase the participation of such individuals in health service and promotion programs;

(3) establish a national minority health resource center to facilitate the exchange of information regarding matters relating to health information and health promotion, preventive health services, and education in the appropriate use of health care, to facilitate access to such information, to assist in the analysis of issues and problems relating to such matters, and to provide technical assistance with respect to the exchange of such information (including facilitating the development of materials for such technical assistance);

(4) support research, demonstrations and evaluations to test new and innovative models, to increase knowledge and understanding of health risk factors, and to develop mechanisms that support better information dissemination, education, prevention, and service delivery to individuals from disadvantaged backgrounds, including racial and ethnic minorities;

(5) coordinate efforts to promote minority health programs and policies in the voluntary and corporate sectors;

(6) develop health information and health promotion materials and teaching programs, including—

(A) models for the training of health professionals;

(B) model curriculums to be used in primary and secondary schools and institutions of higher learning;

(C) materials and programs for the continuing education of health professionals;

(D) materials for public service use by the print and broadcast media; and

(E) materials and programs to assist health care professionals in providing health education to their patients;

(7) assist providers of primary health care and preventive health services in obtaining, with respect to the provision of such care and services, the assistance of bilingual health professionals and other bilingual individuals (including such assistance in the provision of services regarding maternal and

child health, nutrition, mental health, and substance abuse); and

(8) support expansion and enhancement of tertiary perinatal facilities in rural States with infant mortality rates among individuals from disadvantaged backgrounds, including minorities, that are significantly above the national average for such rates.

(c) CERTAIN REQUIREMENTS REGARDING DUTIES.—

(1) EQUITABLE ALLOCATION OF SERVICES.—In carrying out subsection (b), the Secretary shall ensure that services provided under such subsection are equitably allocated among all groups served under this section by the Secretary.

(2) APPROPRIATE CONTEXT OF SERVICES.—In carrying out subsection (b), the Secretary shall ensure that information and services provided under such subsection are provided in the language and cultural context that is most appropriate for the individuals for whom the information and services are intended.

(3) BILINGUAL ASSISTANCE REGARDING HEALTH CARE.—In carrying out subsection (b)(7), the Secretary shall give special consideration to the unique linguistic needs of health care providers serving Asians, and American Samoans and other Pacific Islanders, including such needs regarding particular subpopulations of such groups.

(d) GRANTS AND CONTRACTS REGARDING DUTIES.—

(1) AUTHORITY.—In carrying out subsection (b), the Secretary may make grants to, and enter into cooperative agreements and contracts with, public and nonprofit private entities.

(2) EVALUATION AND DISSEMINATION.—

(A) The Secretary shall, directly or through contracts with public and private entities, provide for evaluations of projects carried out with financial assistance provided under paragraph (1) and for the dissemination of information developed as result of such projects.

(B) Not later than January 20 of fiscal year 1993 and of each second year thereafter, the Secretary shall prepare a report summarizing evaluations carried out under subparagraph (A) during the preceding 2 fiscal years. The report shall be included in the report required in subsection (e) for the fiscal year involved.

(e) REPORTS.—Not later than January 31 of fiscal year 1993 and of each second year thereafter, the Secretary shall submit to the Congress a report describing the activities carried out under this section during the preceding 2 fiscal years.

(f) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$25,000,000 for each of the fiscal year 1991 through 1993.

(2) ALLOCATION OF FUNDS BY SECRETARY.—Of the amounts appropriated under paragraph (1) in excess of \$15,000,000, the Secretary shall make available not less than \$3,000,000 to carry out subsection (b)(7).

OFFICE OF ADOLESCENT HEALTH

SEC. 1708. [300u-7] (a) IN GENERAL.—There is established an Office of Adolescent Health within the Office of the Assistant Secretary for Health, which office shall be headed by a director appointed by the Secretary. The Secretary shall carry out this section acting through the Director of such Office.

(b) DUTIES.—With respect to adolescent health, the Secretary shall—

(1) coordinate all activities within the Department of Health and Human Services that relate to disease prevention, health promotion, preventive health services, and health information and education with respect to the appropriate use of health care, including coordinating—

(A) the design of programs, support for programs, and the evaluation of programs;

(B) the monitoring of trends;

(C) projects of research (including multidisciplinary projects) on adolescent health; and

(D) the training of health providers who work with adolescents, particularly nurse practitioners, physician assistants, and social workers;

(2) coordinate the activities described in paragraph (1) with similar activities in the private sector; and

(3) support projects, conduct research, and disseminate information relating to preventive medicine, health promotion, and physical fitness and sports medicine.

(c) CERTAIN DEMONSTRATION PROJECTS.—

(1) IN GENERAL.—In carrying out subsection (b)(3), the Secretary may make grants to carry out demonstration projects for the purpose of improving adolescent health, including projects to train health care providers in providing services to adolescents and projects to reduce the incidence of violence among adolescents, particularly among minority males.

(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there are authorized to be appropriated \$5,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 1997.

(d) INFORMATION CLEARINGHOUSE.—In carrying out subsection (b), the Secretary shall establish and maintain a National Information Clearinghouse on Adolescent Health to collect and disseminate to health professionals and the general public information on adolescent health.

(e) NATIONAL PLAN.—In carrying out subsection (b), the Secretary shall develop a national plan for improving adolescent health. The plan shall be consistent with the applicable objectives established by the Secretary for the health status of the people of the United States for the year 2000, and shall be periodically reviewed, and as appropriate, revised. The plan, and any revisions in the plan, shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

(f) ADOLESCENT HEALTH.—For purposes of this section, the term “adolescent health”, with respect to adolescents of all ethnic

and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)—

(1) unique to adolescents, or more serious or more prevalent in adolescents;

(2) for which the factors of medical risk or types of medical intervention are different for adolescents, or for which it is unknown whether such factors or types are different for adolescents; or

(3) with respect to which there has been insufficient clinical research involving adolescents as subjects or insufficient clinical data on adolescents.

BIENNIAL REPORT REGARDING NUTRITION AND HEALTH

SEC. 1709. [300u-8] (a) BIENNIAL REPORT.—The Secretary shall require the Surgeon General of the Public Health Service to prepare biennial reports on the relationship between nutrition and health. Such reports may, with respect to such relationship, include any recommendations of the Secretary and the Surgeon General.

(b) SUBMISSION TO CONGRESS.—The Secretary shall ensure that, not later than February 1 of 1995 and of every second year thereafter, a report under subsection (a) is submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

TITLE XVIII—PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH

ESTABLISHMENT OF COMMISSION

SEC. 1801. [300v] (a) ESTABLISHMENT.—(1) There is established the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research¹ (hereinafter in this title referred to as the "Commission") which shall be composed of eleven members appointed by the President. The members of the Commission shall be appointed as follows:

(A) Three of the members shall be appointed from individuals who are distinguished in biomedical or behavioral research.

(B) Three of the members shall be appointed from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care.

(C) Five of the members shall be appointed from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than a biomedical or behavioral science), the social sciences, the humanities, health administration, government, and public affairs.

(2) No individual who is a full-time officer or employee of the United States may be appointed as a member of the Commission. The Secretary of Health, Education, and Welfare, the Secretary of Defense, the Director of Central Intelligence, the Director of the Office of Science and Technology Policy, the Administrator of Veterans' Affairs, and the Director of the National Science Foundation shall each designate an individual to provide liaison with the Commission.

(3) No individual may be appointed to serve as a member of the Commission if the individual has served for two terms of four years each as such a member.

(4) A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

(b) TERMS.—(1) Except as provided in paragraphs (2) and (3), members shall be appointed for terms of four years.

(2) Of the members first appointed—

(A) four shall be appointed for terms of three years, and

(B) three shall be appointed for terms of two years, as designated by the President at the time of appointment.

(3) Any member appointed to fill a vacancy occurring before the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term. A member

¹ Such a Commission was established on December 17, 1979, by Executive Order No. 12184 (44 Fed. Reg. 75091). The Executive Order was revoked on February 25, 1986, by Executive Order No. 12553 (51 Fed. Reg. 7237).

may serve after the expiration of his term until his successor has taken office.

(c) CHAIRMAN.—The Chairman of the Commission shall be appointed by the President, by and with the advice and consent of the Senate, from members of the Commission.

(d) MEETINGS.—(1) Seven members of the Commission shall constitute a quorum for business, but a lesser number may conduct hearings.

(2) The Commission shall meet at the call of the Chairman or at the call of a majority of its members.

(e) COMPENSATION.—(1) Members of the Commission shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Commission.

(2) While away from their homes or regular places of business in the performance of services for the Commission, members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703 of title 5 of the United States Code.

DUTIES OF THE COMMISSION

SEC. 1802. [300v-1] (a) STUDIES.—(1) The Commission shall undertake studies of the ethical and legal implications of—

(A) the requirements for informed consent to participation in research projects and to otherwise undergo medical procedures;

(B) the matter of defining death, including the advisability of developing a uniform definition of death;

(C) voluntary testing, counseling, and information and education programs with respect to genetic diseases and conditions, taking into account the essential equality of all human beings, born and unborn;

(D) the differences in the availability of health services as determined by the income or residence of the persons receiving the services;

(E) current procedures and mechanisms designed (i) to safeguard the privacy of human subjects of behavioral and biomedical research, (ii) to ensure the confidentiality of individually identifiable patient records, and (iii) to ensure appropriate access of patients to information continued¹ in such records,² and

(F) such other matters relating to medicine or biomedical or behavioral research as the President may designate for study by the Commission.

The Commission shall determine the priority and order of the studies required under this paragraph.

(2) The Commission may undertake an investigation or study of any other appropriate matter which relates to medicine or biomedical or behavioral research (including the protection of human

¹ So in original. Probably should be "contained".

² So in original. The comma should probably be a semicolon.

subjects of biomedical or behavioral research) and which is consistent with the purposes of this title on its own initiative or at the request of the head of the Federal agency.

(3) In order to avoid duplication of effort, the Commission may, in lieu of, or as part of, any study or investigation required or otherwise conducted under this subsection, use a study or investigation conducted by another entity if the Commission sets forth its reasons for such use.

(4) Upon the completion of each investigation or study undertaken by the Commission under this subsection (including a study or investigation which merely uses another study or investigation), it shall report its findings (including any recommendations for legislation or administrative action) to the President and the Congress and to each Federal agency to which a recommendation in the report applies.

(b) RECOMMENDATIONS TO AGENCIES.—(1) Within 60 days of the date a Federal agency receives a recommendation from the Commission that the agency take any action with respect to its rules, policies, guidelines, or regulations, the agency shall publish such recommendation in the Federal Register and shall provide opportunity for interested persons to submit written data, views, and arguments with respect to adoption of the recommendation.

(2) Within the 180-day period beginning on the date of such publication, the agency shall determine whether the action proposed by such recommendation is appropriate, and, to the extent that it determines that—

(A) such action is not appropriate, the agency shall, within such time period, provide the Commission with, and publish in the Federal Register, a notice of such determination (including an adequate statement of the reasons for the determination), or

(B) such action is appropriate, the agency shall undertake such action as expeditiously as feasible and shall notify the Commission of the determination and the action undertaken.

(c) REPORT ON PROTECTION OF HUMAN SUBJECTS.—The Commission shall biennially report to the President, the Congress, and appropriate Federal agencies on the protection of human subjects of biomedical and behavioral research. Each such report shall include a review of the adequacy and uniformity (1) of the rules, policies, guidelines, and regulations of all Federal agencies regarding the protection of human subjects of biomedical or behavioral research which such agencies conduct or support, and (2) of the implementation of such rules, policies, guidelines, and regulations by such agencies, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

(d) ANNUAL REPORT.—Not later than December 15 of each year (beginning with 1979) the Commission shall report to the President, the Congress, and appropriate Federal agencies on the activities of the Commission during the fiscal year ending in such year. Each such report shall include a complete list of all recommendations described in subsection (b)(1) made to Federal agencies by the

Commission during the fiscal year and the actions taken, pursuant¹ to subsection (b)(2), by the agencies upon such recommendations, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

(e) PUBLICATIONS.—The Commission may at any time publish and disseminate to the public reports respecting its activities.

(f) DEFINITIONS.—For purposes of this section:

(1) The term "Federal agency" means an authority of the government of the United States, but does not include (A) the Congress, (B) the courts of the United States, and (C) the government of the Commonwealth of Puerto Rico, the government of the District of Columbia, or the government of any territory or possession of the United States.

(2) The term "protection of human subjects" includes the protection of the health, safety, and privacy of individuals.

ADMINISTRATIVE PROVISIONS

SEC. 1803. [300v-2] (a) HEARINGS.—The Commission may for the purpose of carrying out this title hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Commission may deem advisable.

(b) STAFF.—(1) The Commission may appoint and fix the pay of such staff personnel as it deems desirable. Such personnel shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(2) The Commission may procure temporary and intermittent services to the same extent as is authorized by section 3109(b) of title 5 of the United States Code, but at rates for individuals not to exceed the daily equivalent of the annual rate of basis pay in effect for grade GS-18 of the General Schedule.

(3) Upon request of the Commission, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Commission to assist it in carrying out its duties under this title.

(c) CONTRACTS.—The Commission, in performing its duties and functions under this title, may enter into contracts with appropriate public or nonprofit private entities. The authority of the Commission to enter into such contracts is effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(d) INFORMATION.—(1) The Commission may secure directly from any Federal agency information necessary to enable it to carry out this title. Upon request of the Chairman of the Commission, the head of such agency shall furnish such information to the Commission.

(2) The Commission shall promptly arrange for such security clearances for its members and appropriate staff as are necessary to obtain access to classified information needed to carry out its duties under this title.

¹ So in original. Probably should be "pursuant".

(3) The Commission shall not disclose any information reported to or otherwise obtained by the Commission which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of paragraphs (4) and (6) of subsection (b) of such section.

(e) SUPPORT SERVICES.—The Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

AUTHORIZATION OF APPROPRIATIONS; TERMINATION OF COMMISSION

SEC. 1804. [300v-3] (a) AUTHORIZATIONS.—To carry out this title there are authorized to be appropriated \$5,000,000 for the fiscal year ending September 30, 1979, \$5,000,000 for the fiscal year ending September 30, 1980, \$5,000,000 for the fiscal year ending September 30, 1981, and \$5,000,000 for the fiscal year ending September 30, 1982.

(b) FEDERAL ADVISORY COMMITTEE ACT; TERMINATION.—The Commission shall be subject to the Federal Advisory Committee Act, except that, under section 14(a)(1)(B) of such Act, the Commission shall terminate on December 31, 1982.

TITLE XIX—BLOCK GRANTS

PART A—PREVENTIVE HEALTH AND HEALTH SERVICES BLOCK GRANT

AUTHORIZATION OF APPROPRIATIONS

SEC. 1901. [300w] (a) For the purpose of allotments under section 1902, there are authorized to be appropriated \$205,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 1998.

(b) Of the amount appropriated for any fiscal year under subsection (a), at least \$7,000,000 shall be made available for allotments under section 1902(b).

ALLOTMENTS

SEC. 1902. [300w-1] (a)(1) From the amounts appropriated under section 1901 for any fiscal year and available for allotment under this subsection, the Secretary shall allot to each State an amount which bears the same ratio to the available amounts for that fiscal year as the amounts provided by the Secretary under the provisions of law listed in paragraph (2) to the State and entities in the State for fiscal year 1981 bore to the total amount appropriated for such provisions of law for fiscal year 1981.

(2) The provisions of law referred to in paragraph (1) are the following provisions of law as in effect on September 30, 1981:

(A) The authority for grants under section 317 for preventive health service programs for the control of rodents.

(B) The authority for grants under section 317 for establishing and maintaining community and school-based fluoridation programs.

(C) The authority for grants under section 317 for preventive health service programs for hypertension.

(D) Sections 401 and 402 of the Health Services and Centers Amendments of 1978.

(E) Section 314(d).

(F) Section 339(a).

(G) Sections 1202, 1203, and 1204.

(b) From the amount required to be made available under section 1901(b) for allotments under this subsection for any fiscal year, the Secretary shall make allotments to each State on the basis of the population of the State.

(c) To the extent that all the funds appropriated under section 1901 for a fiscal year and available for allotment in such fiscal year are not otherwise allotted to States because—

(1) one or more States have not submitted an application or description of activities in accordance with section 1905 for the fiscal year;

(2) one or more States have notified the Secretary that they do not intend to use the full amount of their allotment; or

(3) some State allotments are offset or repaid under section 1906(b)(3);

such excess shall be allotted among each of the remaining States in proportion to the amount otherwise allotted to such States for the fiscal year without regard to this subsection.

(d)(1) If the Secretary—

(A) receives a request from the governing body of an Indian tribe or tribal organization within any State that funds under this part be provided directly by the Secretary to such tribe or organization, and

(B) determines that the members of such tribe or tribal organization would be better served by means of grants made directly by the Secretary under this part,

the Secretary shall reserve from amounts which would otherwise be allotted to such State under subsection (a) for the fiscal year the amount determined under paragraph (2).

(2) The Secretary shall reserve for the purpose of paragraph (1) from amounts that would otherwise be allotted to such State under subsection (a) an amount equal to the amount which bears the same ratio to the State's allotment for the fiscal year involved as the total amount provided or allotted for fiscal year 1981 by the Secretary to such tribe or tribal organization under the provisions of law referred to in subsection (a) bore to the total amount provided or allotted for such fiscal year by the Secretary to the State and entities (including Indian tribes and tribal organizations) in the State under such provisions of law.

(3) The amount reserved by the Secretary on the basis of a determination under this subsection shall be granted to the Indian tribe or tribal organization serving the individuals for whom such a determination has been made.

(4) In order for an Indian tribe or tribal organization to be eligible for a grant for a fiscal year under this subsection, it shall submit to the Secretary a plan for such fiscal year which meets such criteria as the Secretary may prescribe.

(5) The terms "Indian tribe" and "tribal organization" have the same meaning given such terms in section 4(b) and section 4(c) of the Indian Self-Determination and Education Assistance Act.

(e) The Secretary shall conduct a study for the purpose of devising a formula for the equitable distribution of funds available for allotment to the States under this section. In conducting the study, the Secretary shall take into account—

(1) the financial resources of the various States,

(2) the populations of the States, and

(3) any other factor which the Secretary may consider appropriate.

Before June 30, 1982, the Secretary shall submit a report to the Congress respecting the development of a formula and make such recommendations as the Secretary may deem appropriate in order to ensure the most equitable distribution of funds under allotments under this section.

PAYMENTS UNDER ALLOTMENTS TO STATES

SEC. 1903. [300w-2] (a)(1) For each fiscal year, the Secretary shall make payments, as provided by section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), to each State from its allotment under section 1902 (other than any amount reserved under section 1902(d)) from amounts appropriated for that fiscal year.

(2) Any amount paid to a State for a fiscal year and remaining unobligated at the end of such year shall remain available for the next fiscal year to such State for the purposes for which it was made.

(b) The Secretary, at the request of a State, may reduce the amount of payments under subsection (a) by—

(1) the fair market value of any supplies or equipment furnished the State, and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the State and the amount of any other costs incurred in connection with the detail of such officer or employee, when the furnishing of supplies or equipment or the detail of an officer or employee is for the convenience of and at the request of the State and for the purpose of conducting activities described in section 1904. The amount by which any payment is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment or in detailing the personnel, on which the reduction of the payment is based, and the amount shall be deemed to be part of the payment and shall be deemed to have been paid to the State.

USE OF ALLOTMENTS

SEC. 1904. [300w-3] (a)(1) Except as provided in subsections (b) and (c), payments made to a State under section 1903 may be used for the following:

(A) Activities consistent with making progress toward achieving the objectives established by the Secretary for the health status of the population of the United States for the year 2000 (in this part referred to as "year 2000 health objectives").

(B) Preventive health service programs for the control of rodents and for community and school-based fluoridation programs.

(C) Feasibility studies and planning for emergency medical services systems and the establishment, expansion, and improvement of such systems. Amounts for such systems may not be used for the costs of the operation of the systems or the purchase of equipment for the systems, except that such amounts may be used for the payment of not more than 50 percent of the costs of purchasing communications equipment for the systems. Amounts may be expended for feasibility studies or planning for the trauma-care components of such systems only if the studies or planning, respectively, is consistent with the requirements of section 1213(a).

(D) Providing services to victims of sex offenses and for prevention of sex offenses.

(E) With respect to activities described in any of subparagraphs (A) through (D), related planning, administration, and educational activities.

(F) Monitoring and evaluation of activities carried out under any of subparagraphs (A) through (E)¹

(2) Except as provided in subsection (b), amounts paid to a State under section 1903 from its allotment under section 1902(b) may only be used for providing services to rape victims and for rape prevention.

(3) The Secretary may provide technical assistance to States in planning and operating activities to be carried out under this part.

(b) A State may not use amounts paid to it under section 1903 to—

(1) provide inpatient services,

(2) make cash payments to intended recipients of health services,

(3) purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment,

(4) satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds, or

(5) provide financial assistance to any entity other than a public or nonprofit private entity.

Except as provided in subsection (a)(1)(E), the Secretary may waive the limitation contained in paragraph (3) upon the request of a State if the Secretary finds that there are extraordinary circumstances to justify the waiver and that granting the waiver will assist in carrying out this part.

(c) A State may transfer not more than 7 percent of the amount allotted to the State under section 1902(a) for any fiscal year for use by the State under part B of this title and title V of the Social Security Act in such fiscal year as follows: At any time in the first three quarters of the fiscal year a State may transfer not more than 3 percent of the allotment of the State for the fiscal year for such use, and in the last quarter of a fiscal year a State may transfer for such use not more than the remainder of the amount of its allotment which may be transferred.

(d) Of the amount paid to any State under section 1903, not more than 10 percent paid from each of its allotments under subsections (a) and (b) of section 1902 may be used for administering the funds made available under section 1903. The State will pay from non-Federal sources the remaining costs of administering such funds.

APPLICATION FOR PAYMENTS; STATE PLAN

SEC. 1905. [300w-4] (a) IN GENERAL.—The Secretary may make payments under section 1903 to a State for a fiscal year only if—

¹So in law. See section 102 of Public Law 102-531 (106 Stat. 3470). Subparagraph (F) lacks a period.

(1) the State submits to the Secretary an application for the payments;

(2) the application contains a State plan in accordance with subsection (b);

(3) the application contains the certification described in subsection (c);

(4) the application contains such assurances as the Secretary may require regarding the compliance of the State with the requirements of this part (including assurances regarding compliance with the agreements described in subsection (c)); and

(5) the application is in such form and is submitted by such date as the Secretary may require.

(b) STATE PLAN.—A State plan required in subsection (a)(2) for a fiscal year is in accordance with this subsection if the plan meets the following conditions:

(1) The plan is developed by the State agency with principal responsibility for public health programs, in consultation with the advisory committee established pursuant to subsection (c)(2).

(2) The plan specifies the activities authorized in section 1904 that are to be carried out with payments made to the State under section 1903, including a specification of the year 2000 health objectives for which the State will expend the payments.

(3) The plan specifies the populations in the State for which such activities are to be carried out.

(4) The plan specifies any populations in the State that have a disparate need for such activities.

(5) With respect to each population specified under paragraph (3), the plan contains a strategy for expending such payments to carry out such activities to make progress toward improving the health status of the population, which strategy includes—

(A) a description of the programs and projects to be carried out;

(B) an estimate of the number of individuals to be served by the programs and projects; and

(C) an estimate of the number of public health personnel needed to carry out the strategy.

(6) The plan specifies the amount of such payments to be expended for each of such activities and, with respect to the activity involved—

(A) the amount to be expended for each population specified under paragraph (3); and

(B) the amount to be expended for each population specified under paragraph (4).

(c) STATE CERTIFICATION.—The certification referred to in subsection (a)(3) for a fiscal year is a certification to the Secretary by the chief executive officer of the State involved as follows:

(1)(A) In the development of the State plan required in subsection (a)(2)—

(i) the chief health officer of the State held public hearings on the plan; and

(ii) proposals for the plan were made public in a manner that facilitated comments from public and private entities (including Federal and other public agencies).

(B) The State agrees that, if any revisions are made in such plan during the fiscal year, the State will, with respect to the revisions, hold hearings and make proposals public in accordance with subparagraph (A), and will submit to the Secretary a description of the revisions.

(2) The State has established an advisory committee in accordance with subsection (d).

(3) The State agrees to expend payments under section 1903 only for the activities authorized in section 1904.

(4) The State agrees to expend such payments in accordance with the State plan submitted under subsection (a)(2) (with any revisions submitted to the Secretary under paragraph (1)(B)), including making expenditures to carry out the strategy contained in the plan pursuant to subsection (b)(5).

(5)(A) The State agrees that, in the case of each population for which such strategy is carried out, the State will measure the extent of progress being made toward improving the health status of the population.

(B) The State agrees that—

(i) the State will collect and report data in accordance with section 1906(a); and

(ii) for purposes of subparagraph (A), progress will be measured through use of each of the applicable uniform data items developed by the Secretary under paragraph (2) of such section, or if no such items are applicable, through use of the uniform criteria developed by the Secretary under paragraph (3) of such section.

(6) With respect to the activities authorized in section 1904, the State agrees to maintain State expenditures for such activities at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying to receive payments under section 1903.

(7) The State agrees to establish reasonable criteria to evaluate the effective performance of entities that receive funds from such payments and procedures for procedural and substantive independent State review of the failure by the State to provide funds for any such entity.

(8) The State agrees to permit and cooperate with Federal investigations undertaken in accordance with section 1907.

(9) The State has in effect a system to protect from inappropriate disclosure patient and sex offense victim records maintained by the State in connection with an activity funded under this part or by any entity which is receiving payments from the allotment of the State under this part.

(10) The State agrees to provide the officer of the State government responsible for the administration of the State highway safety program with an opportunity to—

(A) participate in the development of any plan by the State relating to emergency medical services, as such plan relates to highway safety; and

(B) review and comment on any proposal by any State agency to use any Federal grant or Federal payment received by the State for the provision of emergency medical services as such proposal relates to highway safety.

(d) STATE ADVISORY COMMITTEE.—

(1) IN GENERAL.—For purposes of subsection (c)(2), an advisory committee is in accordance with this subsection if such committee is known as the State Preventive Health Advisory Committee (in this subsection referred to as the “Committee”) and the Committee meets the conditions described in the subsequent paragraphs of this subsection.

(2) DUTIES.—A condition under paragraph (1) for a State is that the duties of the Committee are—

(A) to hold public hearings on the State plan required in subsection (a)(2); and

(B) to make recommendations pursuant to subsection (b)(1) regarding the development and implementation of such plan, including recommendations on—

(i) the conduct of assessments of the public health;

(ii) which of the activities authorized in section 1904 should be carried out in the State;

(iii) the allocation of payments made to the State under section 1903;

(iv) the coordination of activities carried out under such plan with relevant programs of other entities; and

(v) the collection and reporting of data in accordance with section 1906(a).

(3) COMPOSITION.—

(A) A condition under paragraph (1) for a State is that the Committee is composed of such members of the general public, and such officials of the health departments of political subdivisions of the State, as may be necessary to provide adequate representation of the general public and of such health departments.

(B) With respect to compliance with subparagraph (A), the membership of advisory committees established pursuant to subsection (c)(2) may include representatives of community-based organizations (including minority community-based organizations), schools of public health, and entities to which the State involved awards grants or contracts to carry out activities authorized in section 1904.

(4) CHAIR; MEETINGS.—A condition under paragraph (1) for a State is that the State public health officer serves as the chair of the Committee, and that the Committee meets not less than twice each fiscal year.

REPORTS, DATA, AND AUDITS

SEC. 1906. [300w-5] (a)(1) For purposes of section 1905(c)(5)(B)(i), a State is collecting and reporting data for a fiscal year in accordance with this subsection if the State submits to the Secretary, not later than February 1 of the succeeding fiscal year, a report that—

(A) describes the purposes for which the State expended payments made to the State under section 1903;

(B) pursuant to section 1905(c)(5)(A), describes the extent of progress made by the State for purposes of such section;

(C) meets the conditions described in the subsequent paragraphs of this subsection; and

(D) contains such additional information regarding activities authorized in section 1904, and is submitted in such form, as the Secretary may require.

(2)(A) The Secretary, in consultation with the States, shall develop sets of data for uniformly defining health status for purposes of the year 2000 health objectives (which sets are in this subsection referred to as "uniform data sets"). Each of such sets shall consist of one or more categories of information (in this subsection individually referred to as a "uniform data item"). The Secretary shall develop formats for the uniform collecting and reporting of information on such items.

(B) A condition under paragraph (1)(C) for a fiscal year is that the State involved will, in accordance with the applicable format under subparagraph (A), collect during such year, and include in the report under paragraph (1), the necessary information for one uniform data item from each of the uniform data sets, which items are selected for the State by the Secretary.

(C) In the case of fiscal year 1995 and each subsequent fiscal year, a condition under paragraph (1) for a State is that the State will, in accordance with the applicable format under subparagraph (A), collect during such year, and include in the report under paragraph (1), the necessary information for each of the uniform data sets appropriate to the year 2000 health objectives that the State has, in the State plan submitted under section 1905 for the fiscal year, specified as a purpose for which payments under section 1903 are to be expended.

(3) The Secretary, in consultation with the States, shall establish criteria for the uniform collection and reporting of data on activities authorized in section 1904 with respect to which no uniform data items exist.

(4) A condition under paragraph (1) for a fiscal year is that the State involved will make copies of the report submitted under such paragraph for the fiscal year available for public inspection, and will upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

(b)(1) Each State shall establish fiscal control and fund accounting procedures as may be necessary to assure the proper disbursement of and accounting for Federal funds paid to the State under section 1903 and funds transferred under section 1904(c) for use under this part.

(2) Each State shall annually audit its expenditures from payments received under section 1903. Such State audits shall be conducted by an entity independent of any agency administering a program funded under this part and, in so far as practical, in accordance with the Comptroller General's standards for auditing governmental organizations, programs, activities, and functions. Within 30 days following the date each audit is completed, the chief execu-

tive officer of the State shall transmit a copy of that audit to the Secretary.

(3) Each State shall, after being provided by the Secretary with adequate notice and opportunity for a hearing within the State, repay to the United States amounts found not to have been expended in accordance with the requirements of this part or the certification provided by the State under section 1905. If such repayment is not made, the Secretary shall, after providing the State with adequate notice and opportunity for a hearing within the State, offset such amounts against the amount of any allotment to which the State is or may become entitled under this part.

(4) The State shall make copies of the reports and audits required by this section available for public inspection within the State.

(5) The Comptroller General of the United States shall, from time to time, evaluate the expenditures by States of grants under this part in order to assure that expenditures are consistent with the provisions of this part and the certification provided by the State under section 1905.

(6) Not later than October 1, 1990, the Secretary shall report to the Congress on the activities of the States that have received funds under this part and may include in the report any recommendations for appropriate changes in legislation.

(c) Title XVII of the Omnibus Budget Reconciliation Act of 1981 shall not apply with respect to audits of funds allotted under this part.

WITHHOLDING

SEC. 1907. [300w-6] (a)(1) The Secretary shall, after adequate notice and an opportunity for a hearing conducted within the affected State, withhold funds from any State which does not use its allotment in accordance with the requirements of this part or the certification provided under section 1905. The Secretary shall withhold such funds until the Secretary finds that the reason for the withholding has been removed and there is reasonable assurance that it will not recur.

(2) The Secretary may not institute proceedings to withhold funds under paragraph (1) unless the Secretary has conducted an investigation concerning whether the State has used its allotment in accordance with the requirements of this part or the certification provided under section 1905. Investigations required by this paragraph shall be conducted within the affected State by qualified investigators.

(3) The Secretary shall respond in an expeditious manner to complaints of a substantial or serious nature that a State has failed to use funds in accordance with the requirements of this part or certifications provided under section 1905.

(4) The Secretary may not withhold funds under paragraph (1) from a State for a minor failure to comply with the requirements of this part or certifications provided under section 1905.

(b)(1) The Secretary shall conduct in several States in each fiscal year investigations of the use of funds received by the States

under this part in order to evaluate compliance with the requirements of this part and certifications provided under section 1905.

(2) The Comptroller General of the United States may conduct investigations of the use of funds received under this part by a State in order to insure compliance with the requirements of this part and certifications provided under section 1905.

(c) Each State, and each entity which has received funds from an allotment made to a State under this part, shall make appropriate books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefor.

(d)(1) In conducting any investigation in a State, the Secretary or the Comptroller General of the United States may not make a request for any information not readily available to such State or an entity which has received funds from an allotment made to the State under this part or make an unreasonable request for information to be compiled, collected, or transmitted in any form not readily available.

(2) Paragraph (1) does not apply to the collection, compilation, or transmittal of data in the course of a judicial proceeding.

NONDISCRIMINATION

SEC. 1908. [300w-7] (a)(1) For the purpose of applying the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975, on the basis of handicap under section 504 of the Rehabilitation Act of 1973, on the basis of sex under title IX of the Education Amendments of 1972, or on the basis of race, color, or national origin under title VI of the Civil Rights Act of 1964, programs and activities funded in whole or in part with funds made available under this part are considered to be programs and activities receiving Federal financial assistance.

(2) No person shall on the ground of sex or religion be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity funded in whole or in part with funds made available under this part.

(b) Whenever the Secretary finds that a State, or an entity that has received a payment from an allotment to a State under section 1902, has failed to comply with a provision of law referred to in subsection (a)(1), with subsection (a)(2), or with an applicable regulation (including one prescribed to carry out subsection (a)(2)), the Secretary shall notify the chief executive officer of the State and shall request him to secure compliance. If within a reasonable period of time, not to exceed sixty days, the chief executive officer fails or refuses to secure compliance, the Secretary may—

(1) refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted,

(2) exercise the powers and functions provided by title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, or section 504 of the Rehabilitation Act of 1973, as may be applicable, or

(3) take such other action as may be provided by law.

(c) When a matter is referred to the Attorney General pursuant to subsection (b)(1), or whenever he has reason to believe that a State or an entity is engaged in a pattern or practice in violation of a provision of law referred to in subsection (a)(1) or in violation of subsection (a)(2), the Attorney General may bring a civil action in any appropriate district court of the United States for such relief as may be appropriate, including injunctive relief.

CRIMINAL PENALTY FOR FALSE STATEMENTS

SEC. 1909. [300w-8] Whoever—

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which payment may be made by a State from funds allotted to the State under this part, or

(2) having knowledge of the occurrence of any event affecting his initial or continued right to any such payment conceals or fails to disclose such event with an intent fraudulently to secure such payment either in a greater amount than is due or when no such payment is authorized,

shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

EMERGENCY MEDICAL SERVICES FOR CHILDREN

SEC. 1910. [300w-9] (a) For activities in addition to the activities which may be carried out by States under section 1904(a)(1)(F), the Secretary may make grants to States or accredited schools of medicine in States to support a program of demonstration projects for the expansion and improvement of emergency medical services for children who need treatment for trauma or critical care. Any grant made under this subsection shall be for not more than a two-year period, subject to annual evaluation by the Secretary. Only one grant under this subsection may be made in a State (to a State or to a school of medicine in such State) in any fiscal year.

(b) The Secretary may renew a grant made under subsection (a) for one additional one-year period only if the Secretary determines that renewal of such grant will provide significant benefits through the collection, analysis, and dissemination of information or data which will be useful to States in which grants under such subsection have not been made.

(c) For purposes of this section—

(1) the term "school of medicine" has the same meaning as in section 701(4); and

(2) the term "accredited" has the same meaning as in section 701(5).

(d) To carry out this section, there are authorized to be appropriated \$2,000,000 for fiscal year 1985 and for each of the two succeeding fiscal years, \$3,000,000 for fiscal year 1989, \$4,000,000 for fiscal year 1990, \$5,000,000 for each of the fiscal years 1991 and

1992, and such sums as may be necessary for each of the fiscal years 1993 through 1997.¹

PART B—BLOCK GRANTS REGARDING MENTAL HEALTH AND SUBSTANCE ABUSE

Subpart I—Block Grants for Community Mental Health Services

SEC. 1911. [300x-1] FORMULA GRANTS TO STATES.

(a) **IN GENERAL.**—For the purpose described in subsection (b), the Secretary, acting through the Director of the Center for Mental Health Services, shall make an allotment each fiscal year for each State in an amount determined in accordance with section 1918. The Secretary shall make a grant to the State of the allotment made for the State for the fiscal year if the State submits to the Secretary an application in accordance with section 1917.

(b) **PURPOSE OF GRANTS.**—A funding agreement for a grant under subsection (a) is that, subject to section 1916, the State involved will expend the grant only for the purpose of—

- (1) carrying out the plan submitted under section 1912(a) by the State for the fiscal year involved;
- (2) evaluating programs and services carried out under the plan; and
- (3) planning, administration, and educational activities related to providing services under the plan.

¹Section 40151 of Public Law 103-322 (108 Stat. 1920) provides for a new section 1910A in the "Public Health and Human Services Act". The amendment has not been executed to this Act, as this Act is the Public Health Service Act.

Such section 40151 provides as follows: "Part A of title XIX of the Public Health and Human Services Act (42 U.S.C. 300w et seq.) is amended by adding at the end the following new section:

'SEC. 1910A. USE OF ALLOTMENTS FOR RAPE PREVENTION EDUCATION.

(a) **PERMITTED USE.**—Notwithstanding section 1904(a)(1), amounts transferred by the State for use under this part may be used for rape prevention and education programs conducted by rape crisis centers or similar nongovernmental nonprofit entities for—

- '(1) educational seminars;
- '(2) the operation of hotlines;
- '(3) training programs for professionals;
- '(4) the preparation of informational materials; and
- '(5) other efforts to increase awareness of the facts about, or to help prevent, sexual assault, including efforts to increase awareness in underserved racial, ethnic, and language minority communities.

(b) **TARGETING OF EDUCATION PROGRAMS.**—States providing grant monies must ensure that at least 25 percent of the monies are devoted to education programs targeted for middle school, junior high school, and high school students.

(c) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to carry out this section—

- '(1) \$35,000,000 for fiscal year 1996;
- '(2) \$35,000,000 for fiscal year 1997;
- '(3) \$45,000,000 for fiscal year 1998;
- '(4) \$45,000,000 for fiscal year 1999; and
- '(5) \$45,000,000 for fiscal year 2000.

(d) **LIMITATION.**—Funds authorized under this section may only be used for providing rape prevention and education programs.

(e) **DEFINITION.**—For purposes of this section, the term 'rape prevention and education' includes education and prevention efforts directed at offenses committed by offenders who are not known to the victim as well as offenders who are known to the victim.

(f) **TERMS.**—The Secretary shall make allotments to each State on the basis of the population of the State, and subject to the conditions provided in this section and sections 1904 through 1909."

SEC. 1912. [300x-2] STATE PLAN FOR COMPREHENSIVE COMMUNITY MENTAL HEALTH SERVICES FOR CERTAIN INDIVIDUALS.

(a) IN GENERAL.—The Secretary may make a grant under section 1911 only if—

(1) the State involved submits to the Secretary a plan for providing comprehensive community mental health services to adults with a serious mental illness and to children with a serious emotional disturbance;

(2) the plan meets the criteria specified in subsection (b); and

(3) the plan is approved by the Secretary.

(b) CRITERIA FOR PLAN.—With respect to the provision of comprehensive community mental health services to individuals who are either adults with a serious mental illness or children with a serious emotional disturbance, the criteria referred to in subsection (a) regarding a plan are as follows:

(1) The plan provides for the establishment and implementation of an organized community-based system of care for such individuals.

(2) The plan contains quantitative targets to be achieved in the implementation of such system, including the numbers of such individuals residing in the areas to be served under such system.

(3) The plan describes available services, available treatment options, and available resources (including Federal, State and local public services and resources, and to the extent practicable, private services and resources) to be provided such individuals.

(4) The plan describes health and mental health services, rehabilitation services, employment services, housing services, educational services, medical and dental care, and other support services to be provided to such individuals with Federal, State and local public and private resources to enable such individuals to function outside of inpatient or residential institutions to the maximum extent of their capabilities, including services to be provided by local school systems under the Individuals with Disabilities Education Act.

(5) The plan describes the financial resources and staffing necessary to implement the requirements of such plan, including programs to train individuals as providers of mental health services, and the plan emphasizes training of providers of emergency health services regarding mental health.

(6) The plan provides for activities to reduce the rate of hospitalization of such individuals.

(7)(A) Subject to subparagraph (B), the plan requires the provision of case management services to each such individual in the State who receives substantial amounts of public funds or services.

(B) The plan may provide that the requirement of subparagraph (A) will not be substantially completed until the end of fiscal year 1993.

(8) The plan provides for the establishment and implementation of a program of outreach to, and services for, such individuals who are homeless.

(9) In the case of children with a serious emotional disturbance, the plan—

(A) subject to subparagraph (B), provides for a system of integrated social services, educational services, juvenile services, and substance abuse services that, together with health and mental health services, will be provided in order for such children to receive care appropriate for their multiple needs (which system includes services provided under the Individuals with Disabilities Education Act);

(B) provides that the grant under section 1911 for the fiscal year involved will not be expended to provide any service of such system other than comprehensive community mental health services; and

(C) provides for the establishment of a defined geographic area for the provision of the services of such system.

(10) The plan describes the manner in which mental health services will be provided to individuals residing in rural areas.

(11) The plan contains an estimate of the incidence and prevalence in the State of serious mental illness among adults and serious emotional disturbance among children.

(12) The plan contains a description of the manner in which the State intends to expend the grant under section 1911 for the fiscal year involved to carry out the provisions of the plan required in paragraphs (1) through (11).

(c) DEFINITIONS REGARDING MENTAL ILLNESS AND EMOTIONAL DISTURBANCE; METHODS FOR ESTIMATE OF INCIDENCE AND PREVALENCE.—

(1) ESTABLISHMENT BY SECRETARY OF DEFINITIONS; DISSEMINATION.—For purposes of this subpart, the Secretary shall establish definitions for the terms “adults with a serious mental illness” and “children with a serious emotional disturbance”. The Secretary shall disseminate the definitions to the States.

(2) STANDARDIZED METHODS.—The Secretary shall establish standardized methods for making the estimates required in subsection (b)(11) with respect to a State. A funding agreement for a grant under section 1911 for the State is that the State will utilize such methods in making the estimates.

(3) DATE CERTAIN FOR COMPLIANCE BY SECRETARY.—Not later than 90 days after the date of the enactment of the ADAMHA Reorganization Act¹, the Secretary shall establish the definitions described in paragraph (1), shall begin dissemination of the definitions to the States, and shall establish the standardized methods described in paragraph (2).

(d) REQUIREMENT OF IMPLEMENTATION OF PLAN.—

(1) COMPLETE IMPLEMENTATION.—Except as provided in paragraph (2), in making a grant under section 1911 to a State for a fiscal year, the Secretary shall make a determination of the extent to which the State has implemented the plan required in subsection (a). If the Secretary determines that a

¹ Enacted July 10, 1992.

State has not completely implemented the plan, the Secretary shall reduce the amount of the allotment under section 1911 for the State for the fiscal year involved by an amount equal to 10 percent of the amount determined under section 1918 for the State for the fiscal year.

(2) SUBSTANTIAL IMPLEMENTATION AND GOOD FAITH EFFORT REGARDING FISCAL YEAR 1993.—

(A) In making a grant under section 1911 to a State for fiscal year 1993, the Secretary shall make a determination of the extent to which the State has implemented the plan required in subsection (a). If the Secretary determines that the State has not substantially implemented the plan, the Secretary shall, subject to subparagraph (B), reduce the amount of the allotment under section 1911 for the State for such fiscal year by an amount equal to 10 percent of the amount determined under section 1918 for the State for the fiscal year.

(B) In carrying out subparagraph (A), if the Secretary determines that the State is making a good faith effort to implement the plan required in subsection (a), the Secretary may make a reduction under such subparagraph in an amount that is less than the amount specified in such subparagraph, except that the reduction may not be made in an amount that is less than 5 percent of the amount determined under section 1918 for the State for fiscal year 1993.

SEC. 1913. [300x-3] CERTAIN AGREEMENTS.

(a) ALLOCATION FOR SYSTEMS OF INTEGRATED SERVICES FOR CHILDREN.—

(1) IN GENERAL.—With respect to children with a serious emotional disturbance, a funding agreement for a grant under section 1911 is that—

(A) in the case of a grant for fiscal year 1993, the State involved will expend not less than 10 percent of the grant to increase (relative to fiscal year 1992) funding for the system of integrated services described in section 1912(b)(9);

(B) in the case of a grant for fiscal year 1994, the State will expend not less than 10 percent of the grant to increase (relative to fiscal year 1993) funding for such system; and

(C) in the case of a grant for any subsequent fiscal year, the State will expend for such system not less than an amount equal to the amount expended by the State for fiscal year 1994.

(2) WAIVER.—

(A) Upon the request of a State, the Secretary may provide to the State a waiver of all or part of the requirement established in paragraph (1) if the Secretary determines that the State is providing an adequate level of comprehensive community mental health services for children with a serious emotional disturbance, as indicated by a comparison of the number of such children for which such

services are sought with the availability in the State of the services.

(B) The Secretary shall approve or deny a request for a waiver under subparagraph (A) not later than 120 days after the date on which the request is made.

(C) Any waiver provided by the Secretary under subparagraph (A) shall be applicable only to the fiscal year involved.

(b) PROVIDERS OF SERVICES.—A funding agreement for a grant under section 1911 for a State is that, with respect to the plan submitted under section 1912(a) for the fiscal year involved—

(1) services under the plan will be provided only through appropriate, qualified community programs (which may include community mental health centers, child mental-health programs, psychosocial rehabilitation programs, mental health peer-support programs, and mental-health primary consumer-directed programs); and

(2) services under the plan will be provided through community mental health centers only if the centers meet the criteria specified in subsection (c).

(c) CRITERIA FOR MENTAL HEALTH CENTERS.—The criteria referred to in subsection (b)(2) regarding community mental health centers are as follows:

(1) With respect to mental health services, the centers provide services as follows:

(A) Services principally to individuals residing in a defined geographic area (hereafter in this subsection referred to as a "service area").

(B) Outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of the service areas of the centers who have been discharged from inpatient treatment at a mental health facility.

(C) 24-hour-a-day emergency care services.

(D) Day treatment or other partial hospitalization services, or psychosocial rehabilitation services.

(E) Screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

(2) The mental health services of the centers are provided, within the limits of the capacities of the centers, to any individual residing or employed in the service area of the center regardless of ability to pay for such services.

(3) The mental health services of the centers are available and accessible promptly, as appropriate and in a manner which preserves human dignity and assures continuity and high quality care.

SEC. 1914. [300x-4] STATE MENTAL HEALTH PLANNING COUNCIL.

(a) IN GENERAL.—A funding agreement for a grant under section 1911 is that the State involved will establish and maintain a State mental health planning council in accordance with the conditions described in this section.

(b) DUTIES.—A condition under subsection (a) for a Council is that the duties of the Council are—

(1) to review plans provided to the Council pursuant to section 1915(a) by the State involved and to submit to the State any recommendations of the Council for modifications to the plans;

(2) to serve as an advocate for adults with a serious mental illness, children with a severe emotional disturbance, and other individuals with mental illnesses or emotional problems; and

(3) to monitor, review, and evaluate, not less than once each year, the allocation and adequacy of mental health services within the State.

(c) MEMBERSHIP.—

(1) IN GENERAL.—A condition under subsection (a) for a Council is that the Council be composed of residents of the State, including representatives of—

(A) the principal State agencies with respect to—

(i) mental health, education, vocational rehabilitation, criminal justice, housing, and social services; and

(ii) the development of the plan submitted pursuant to title XIX of the Social Security Act;

(B) public and private entities concerned with the need, planning, operation, funding, and use of mental health services and related support services;

(C) adults with serious mental illnesses who are receiving (or have received) mental health services; and

(D) the families of such adults or families of children with emotional disturbance.

(2) CERTAIN REQUIREMENTS.—A condition under subsection (a) for a Council is that—

(A) with respect to the membership of the Council, the ratio of parents of children with a serious emotional disturbance to other members of the Council is sufficient to provide adequate representation of such children in the deliberations of the Council; and

(B) not less than 50 percent of the members of the Council are individuals who are not State employees or providers of mental health services.

(d) DEFINITION.—For purposes of this section, the term "Council" means a State mental health planning council.

SEC. 1915. [300x-4] ADDITIONAL PROVISIONS.

(a) REVIEW OF STATE PLAN BY MENTAL HEALTH PLANNING COUNCIL.—The Secretary may make a grant under section 1911 to a State only if—

(1) the plan submitted under section 1912(a) with respect to the grant has been reviewed by the State mental health planning council under section 1914; and

(2) the State submits to the Secretary any recommendations received by the State from such council for modifications to the plan (without regard to whether the State has made the recommended modifications).

(b) **MAINTENANCE OF EFFORT REGARDING STATE EXPENDITURES FOR MENTAL HEALTH.**—

(1) **IN GENERAL.**—A funding agreement for a grant under section 1911 is that the State involved will maintain State expenditures for community mental health services at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying for the grant.

(2) **WAIVER.**—The Secretary may, upon the request of a State, waive the requirement established in paragraph (1) if the Secretary determines that extraordinary economic conditions in the State justify the waiver.

(3) **NONCOMPLIANCE BY STATE.**—

(A) In making a grant under section 1911 to a State for a fiscal year, the Secretary shall make a determination of whether, for the previous fiscal year, the State maintained material compliance with the agreement made under paragraph (1). If the Secretary determines that a State has failed to maintain such compliance, the Secretary shall reduce the amount of the allotment under section 1911 for the State for the fiscal year for which the grant is being made by an amount equal to the amount constituting such failure for the previous fiscal year.

(B) The Secretary may make a grant under section 1911 for a fiscal year only if the State involved submits to the Secretary information sufficient for the Secretary to make the determination required in subparagraph (A).

SEC. 1916. [300x-5] RESTRICTIONS ON USE OF PAYMENTS.

(a) **IN GENERAL.**—A funding agreement for a grant under section 1911 is that the State involved will not expend the grant—

(1) to provide inpatient services;

(2) to make cash payments to intended recipients of health services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(b) **LIMITATION ON ADMINISTRATIVE EXPENSES.**—A funding agreement for a grant under section 1911 is that the State involved will not expend more than 5 percent of the grant for administrative expenses with respect to the grant.

SEC. 1917. [300x-6] APPLICATION FOR GRANT.

(a) **IN GENERAL.**—For purposes of section 1911, an application for a grant under such section for a fiscal year in accordance with¹ this section if, subject to subsection (b)—

¹So in law. See section 201 of Public Law 102-321 (106 Stat. 378). Probably should be "is in accordance with".

(1) the State involved submits the application not later than the date specified by the Secretary as being the date after which applications for such a grant will not be considered (in any case in which the Secretary specifies such a date);

(2) the application contains each funding agreement that is described in this subpart or subpart III for such a grant (other than any such agreement that is not applicable to the State);

(3) the agreements are made through certification from the chief executive officer of the State;

(4) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary;

(5) the application contains the plan required in section 1912(a), the information required in section 1915(b)(3)(B), and the report required in section 1942(a);

(6) the application contains recommendations in compliance with section 1915(a), or if no such recommendations are received by the State, the application otherwise demonstrates compliance with such section; and

(7) the application (including the plan under section 1912(a)) is otherwise in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this subpart.

(b) **WAIVERS REGARDING CERTAIN TERRITORIES.**—In the case of any territory of the United States whose allotment under section 1911 for the fiscal year is the amount specified in section 1918(c)(2)(B), the Secretary may waive such provisions of this subpart and subpart III as the Secretary determines to be appropriate, other than the provisions of section 1916.

SEC. 1918. [300x-7] DETERMINATION OF AMOUNT OF ALLOTMENT.

(a) **STATES.**—

(1) **DETERMINATION UNDER FORMULA.**—Subject to subsection (b), the Secretary shall determine the amount of the allotment required in section 1911 for a State for a fiscal year in accordance with the following formula:

$$A \left(\frac{X}{U} \right)$$

(2) **DETERMINATION OF TERM "A".**—For purposes of paragraph (1), the term "A" means the difference between—

(A) the amount appropriated under section 1920(a) for allotments under section 1911 for the fiscal year involved; and

(B) an amount equal to 1.5 percent of the amount referred to in subparagraph (A).

(3) **DETERMINATION OF TERM "U".**—For purposes of paragraph (1), the term "U" means the sum of the respective terms "X" determined for the States under paragraph (4).

(4) **DETERMINATION OF TERM "X".**—For purposes of paragraph (1), the term "X" means the product of—

(A) an amount equal to the product of—

- (i) the term "P", as determined for the State involved under paragraph (5); and
- (ii) the factor determined under paragraph (8) for the State; and
- (B) the greater of—
 - (i) 0.4; and
 - (ii) an amount equal to an amount determined for the State in accordance with the following formula:

$$1 - .35 \left(\frac{R\%}{P\%} \right)$$

(5) DETERMINATION OF TERM "P".—

(A) For purposes of paragraph (4), the term "P" means the sum of—

- (i) an amount equal to the product of 0.107 and the number of individuals in the State who are between 18 and 24 years of age (inclusive);
- (ii) an amount equal to the product of 0.166 and the number of individuals in the State who are between 25 and 44 years of age (inclusive);
- (iii) an amount equal to the product of 0.099 and the number of individuals in the State who are between 45 and 64 years of age (inclusive); and
- (iv) an amount equal to the product of 0.082 and the number of individuals in the State who are 65 years of age or older.

(B) With respect to data on population that is necessary for purposes of making a determination under subparagraph (A), the Secretary shall use the most recent data that is available from the Secretary of Commerce pursuant to the decennial census and pursuant to reasonable estimates by such Secretary of changes occurring in the data in the ensuing period.

(6) DETERMINATION OF TERM "R%".—

(A) For purposes of paragraph (4), the term "R%", except as provided in subparagraph (D), means the percentage constituted by the ratio of the amount determined under subparagraph (B) for the State involved to the amount determined under subparagraph (C).

(B) The amount determined under this subparagraph for the State involved is the quotient of—

- (i) the most recent 3-year arithmetic mean of the total taxable resources of the State, as determined by the Secretary of the Treasury; divided by
- (ii) the factor determined under paragraph (8) for the State.

(C) The amount determined under this subparagraph is the sum of the respective amounts determined for the States under subparagraph (B) (including the District of Columbia).

(D)(i) In the case of the District of Columbia, for purposes of paragraph (4), the term "R%" means the percentage constituted by the ratio of the amount determined under clause (ii) for such District to the amount determined under clause (iii).

(ii) The amount determined under this clause for the District of Columbia is the quotient of—

(I) the most recent 3-year arithmetic mean of total personal income in such District, as determined by the Secretary of Commerce; divided by

(II) the factor determined under paragraph (8) for the District.

(iii) The amount determined under this clause is the sum of the respective amounts determined for the States (including the District of Columbia) by making, for each State, the same determination as is described in clause (ii) for the District of Columbia.

(7) DETERMINATION OF TERM "P%".—For purposes of paragraph (4), the term "P%" means the percentage constituted by the ratio of the term "P" determined under paragraph (5) for the State involved to the sum of the respective terms "P" determined for the States.

(8) DETERMINATION OF CERTAIN FACTOR.—

(A) The factor determined under this paragraph for the State involved is a factor whose purpose is to adjust the amount determined under clause (i) of paragraph (4)(A), and the amounts determined under each of subparagraphs (B)(i) and (D)(ii)(I) of paragraph (6), to reflect the differences that exist between the State and other States in the costs of providing comprehensive community mental health services to adults with a serious mental illness and to children with a serious emotional disturbance.

(B) Subject to subparagraph (C), the factor determined under this paragraph and in effect for the fiscal year involved shall be determined according to the methodology described in the report entitled "Adjusting the Alcohol, Drug Abuse and Mental Health Services Block Grant Allocations for Poverty Populations and Cost of Service", dated March 30, 1990, and prepared by Health Economics Research, a corporation, pursuant to a contract with the National Institute on Drug Abuse.

(C) The factor determined under this paragraph for the State involved may not for any fiscal year be greater than 1.1 or less than 0.9.

(D)(i) Not later than October 1, 1992, the Secretary, after consultation with the Comptroller General, shall in accordance with this section make a determination for each State of the factor that is to be in effect for the State under this paragraph. The factor so determined shall remain in effect through fiscal year 1994, and shall be recalculated every third fiscal year thereafter.

(ii) After consultation with the Comptroller General, the Secretary shall, through publication in the Federal Register, periodically make such refinements in the meth-

odology referred to in subparagraph (B) as are consistent with the purpose described in subparagraph (A).

(b) **MINIMUM ALLOTMENTS FOR STATES.**—For each of the fiscal years 1993 and 1994, the amount of the allotment required in section 1911 for a State for the fiscal year involved shall be the greater of—

(1) the amount determined under subsection (a) for the State for the fiscal year; and

(2) an amount equal to 20.6 percent of the amount received by the State from allotments made pursuant to this part for fiscal year 1992 (including reallootments under section 205(a) of the ADAMHA Reorganization Act).

(c) **TERRITORIES.**—

(1) **DETERMINATION UNDER FORMULA.**—Subject to paragraphs (2) and (4), the amount of an allotment under section 1911 for a territory of the United States for a fiscal year shall be the product of—

(A) an amount equal to the amounts reserved under paragraph (3) for the fiscal year; and

(B) a percentage equal to the quotient of—

(i) the civilian population of the territory, as indicated by the most recently available data; divided by

(ii) the aggregate civilian population of the territories of the United States, as indicated by such data.

(2) **MINIMUM ALLOTMENT FOR TERRITORIES.**—The amount of an allotment under section 1911 for a territory of the United States for a fiscal year shall be the greater of—

(A) the amount determined under paragraph (1) for the territory for the fiscal year;

(B) \$50,000; and

(C) with respect to fiscal years 1993 and 1994, an amount equal to 20.6 percent of the amount received by the territory from allotments made pursuant to this part for fiscal year 1992.

(3) **RESERVATION OF AMOUNTS.**—The Secretary shall each fiscal year reserve for the territories of the United States 1.5 percent of the amounts appropriated under section 1920(a) for allotments under section 1911 for the fiscal year.

(4) **AVAILABILITY OF DATA ON POPULATION.**—With respect to data on the civilian population of the territories of the United States, if the Secretary determines for a fiscal year that recent such data for purposes of paragraph (1)(B) do not exist regarding a territory, the Secretary shall for such purposes estimate the civilian population of the territory by modifying the data on the territory to reflect the average extent of change occurring during the ensuing period in the population of all territories with respect to which recent such data do exist.

(5) **APPLICABILITY OF CERTAIN PROVISIONS.**—For purposes of subsection (a), the term “State” does not include the territories of the United States.

SEC. 1919. [300x-8] DEFINITIONS.

For purposes of this subpart:

(1) The terms "adults with a serious mental illness" and "children with a serious emotional disturbance" have the meanings given such terms under section 1912(c)(1).

(2) The term "funding agreement", with respect to a grant under section 1911 to a State, means that the Secretary may make such a grant only if the State makes the agreement involved.

SEC. 1920. [300x-9] FUNDING.

(a) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this subpart, and subpart III and section 505 with respect to mental health, there are authorized to be appropriated \$450,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(b) **ALLOCATIONS FOR TECHNICAL ASSISTANCE, DATA COLLECTION, AND PROGRAM EVALUATION.**—

(1) **IN GENERAL.**—For the purpose of carrying out section 1948(a) with respect to mental health and the purposes specified in paragraphs (2) and (3), the Secretary shall obligate 5 percent of the amounts appropriated under subsection (a) for a fiscal year.

(2) **DATA COLLECTION.**—The purpose specified in this paragraph is carrying out section 505 with respect to mental health.

(3) **PROGRAM EVALUATION.**—The purpose specified in this paragraph is the conduct of evaluations of prevention and treatment programs and services with respect to mental health to determine methods for improving the availability and quality of such programs and services.

Subpart II—Block Grants for Prevention and Treatment of Substance Abuse

SEC. 1921. [300x-21] FORMULA GRANTS TO STATES.

(a) **IN GENERAL.**—For the purpose described in subsection (b), the Secretary, acting through the Center for Substance Abuse Treatment, shall make an allotment each fiscal year for each State in an amount determined in accordance with section 1933. The Secretary shall make a grant to the State of the allotment made for the State for the fiscal year if the State submits to the Secretary an application in accordance with section 1932.

(b) **AUTHORIZED ACTIVITIES.**—A funding agreement for a grant under subsection (a) is that, subject to section 1931, the State involved will expend the grant only for the purpose of planning, carrying out, and evaluating activities to prevent and treat substance abuse and for related activities authorized in section 1924.

SEC. 1922. [300x-22] CERTAIN ALLOCATIONS.

(a) **ALLOCATIONS REGARDING ALCOHOL AND OTHER DRUGS.**—A funding agreement for a grant under section 1921 is that, in expending the grant, the State involved will expend—

(1) not less than 35 percent for prevention and treatment activities regarding alcohol; and

(2) not less than 35 percent for prevention and treatment activities regarding other drugs.

(b) ALLOCATION REGARDING PRIMARY PREVENTION PROGRAMS.—A funding agreement for a grant under section 1921 is that, in expending the grant, the State involved—

(1) will expend not less than 20 percent for programs for individuals who do not require treatment for substance abuse, which programs—

(A) educate and counsel the individuals on such abuse; and

(B) provide for activities to reduce the risk of such abuse by the individuals;

(2) will, in carrying out paragraph (1)—

(A) give priority to programs for populations that are at risk of developing a pattern of such abuse; and

(B) ensure that programs receiving priority under subparagraph (A) develop community-based strategies for the prevention of such abuse, including strategies to discourage the use of alcoholic beverages and tobacco products by individuals to whom it is unlawful to sell or distribute such beverages or products.

(c) ALLOCATIONS REGARDING WOMEN.—

(1) IN GENERAL.—Subject to paragraph (2), a funding agreement for a grant under section 1921 for a fiscal year is that—

(A) in the case of a grant for fiscal year 1993, the State involved will expend not less than 5 percent of the grant to increase (relative to fiscal year 1992) the availability of treatment services designed for pregnant women and women with dependent children (either by establishing new programs or expanding the capacity of existing programs);

(B) in the case of a grant for fiscal year 1994, the State will expend not less than 5 percent of the grant to so increase (relative to fiscal year 1993) the availability of such services for such women; and

(C) in the case of a grant for any subsequent fiscal year, the State will expend for such services for such women not less than an amount equal to the amount expended by the State for fiscal year 1994.

(2) WAIVER.—

(A) Upon the request of a State, the Secretary may provide to the State a waiver of all or part of the requirement established in paragraph (1) if the Secretary determines that the State is providing an adequate level of treatments services for women described in such paragraph, as indicated by a comparison of the number of such women seeking the services with the availability in the State of the services.

(B) The Secretary shall approve or deny a request for a waiver under subparagraph (A) not later than 120 days after the date on which the request is made.

(C) Any waiver provided by the Secretary under subparagraph (A) shall be applicable only to the fiscal year involved.

(3) **CHILDCARE AND PRENATAL CARE.**—A funding agreement for a grant under section 1921 for a State is that each entity providing treatment services with amounts reserved under paragraph (1) by the State will, directly or through arrangements with other public or nonprofit private entities, make available prenatal care to women receiving such services and, while the women are receiving the services, childcare.

SEC. 1923. [300x-23] INTRAVENOUS SUBSTANCE ABUSE.

(a) CAPACITY OF TREATMENT PROGRAMS.—

(1) **NOTIFICATION OF REACHING CAPACITY.**—A funding agreement for a grant under section 1921 is that the State involved will, in the case of programs of treatment for intravenous drug abuse, require that any such program receiving amounts from the grant, upon reaching 90 percent of its capacity to admit individuals to the program, provide to the State a notification of such fact.

(2) **PROVISION OF TREATMENT.**—A funding agreement for a grant under section 1921 is that the State involved will, with respect to notifications under paragraph (1), ensure that each individual who requests and is in need of treatment for intravenous drug abuse is admitted to a program of such treatment not later than—

(A) 14 days after making the request for admission to such a program; or

(B) 120 days after the date of such request, if no such program has the capacity to admit the individual on the date of such request and if interim services are made available to the individual not later than 48 hours after such request.

(b) OUTREACH REGARDING INTRAVENOUS SUBSTANCE ABUSE.—A funding agreement for a grant under section 1921 is that the State involved, in providing amounts from the grant to any entity for treatment services for intravenous drug abuse, will require the entity to carry out activities to encourage individuals in need of such treatment to undergo treatment.

SEC. 1924. [300x-24] REQUIREMENTS REGARDING TUBERCULOSIS AND HUMAN IMMUNODEFICIENCY VIRUS.

(a) TUBERCULOSIS.—

(1) **IN GENERAL.**—A funding agreement for a grant under section 1921 is that the State involved will require that any entity receiving amounts from the grant for operating a program of treatment for substance abuse—

(A) will, directly or through arrangements with other public or nonprofit private entities, routinely make available tuberculosis services to each individual receiving treatment for such abuse; and

(B) in the case of an individual in need of such treatment who is denied admission to the program on the basis of the lack of the capacity of the program to admit the individual, will refer the individual to another provider of tuberculosis services.

(2) TUBERCULOSIS SERVICES.—For purposes of paragraph (1), the term “tuberculosis services”, with respect to an individual, means—

(A) counseling the individual with respect to tuberculosis;

(B) testing to determine whether the individual has contracted such disease and testing to determine the form of treatment for the disease that is appropriate for the individual; and

(C) providing such treatment to the individual.

(b) HUMAN IMMUNODEFICIENCY VIRUS.—

(1) REQUIREMENT FOR CERTAIN STATES.—In the case of a State described in paragraph (2), a funding agreement for a grant under section 1921 is that—

(A) with respect to individuals undergoing treatment for substance abuse, the State will, subject to paragraph (3), carry out 1 or more projects to make available to the individuals early intervention services for HIV disease at the sites at which the individuals are undergoing such treatment;

(B) for the purpose of providing such early intervention services through such projects, the State will make available from the grant the percentage that is applicable for the State under paragraph (4); and

(C) the State will, subject to paragraph (5), carry out such projects only in geographic areas of the State that have the greatest need for the projects.

(2) DESIGNATED STATES.—For purposes of this subsection, a State described in this paragraph is any State whose rate of cases of acquired immune deficiency syndrome is 10 or more such cases per 100,000 individuals (as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control for the most recent calendar year for which such data are available).

(3) USE OF EXISTING PROGRAMS REGARDING SUBSTANCE ABUSE.—With respect to programs that provide treatment services for substance abuse, a funding agreement for a grant under section 1921 for a designated State is that each such program participating in a project under paragraph (1) will be a program that began operation prior to the fiscal year for which the State is applying to receive the grant. A program that so began operation may participate in a project under paragraph (1) without regard to whether the program has been providing early intervention services for HIV disease.

(4) APPLICABLE PERCENTAGE REGARDING EXPENDITURES FOR SERVICES.—

(A)(i) For purposes of paragraph (1)(B), the percentage that is applicable under this paragraph for a designated State is, subject to subparagraph (B), the percentage by which the amount of the grant under section 1921 for the State for the fiscal year involved is an increase over the amount specified in clause (ii).

(ii) The amount specified in this clause is the amount that was reserved by the designated State involved from

the allotment of the State under section 1912A for fiscal year 1991 in compliance with section 1916(c)(6)(A)(ii) (as such sections were in effect for such fiscal year).

(B) If the percentage determined under subparagraph (A) for a designated State for a fiscal year is less than 2 percent (including a negative percentage, in the case of a State for which there is no increase for purposes of such subparagraph), the percentage applicable under this paragraph for the State is 2 percent. If the percentage so determined is 2 percent or more, the percentage applicable under this paragraph for the State is the percentage determined under subparagraph (A), subject to not exceeding 5 percent.

(5) REQUIREMENT REGARDING RURAL AREAS.—

(A) A funding agreement for a grant under section 1921 for a designated State is that, if the State will carry out 2 or more projects under paragraph (1), the State will carry out 1 such project in a rural area of the State, subject to subparagraph (B).

(B) The Secretary shall waive the requirement established in subparagraph (A) if the State involved certifies to the Secretary that—

(i) there is insufficient demand in the State to carry out a project under paragraph (1) in any rural area of the State; or

(ii) there are no rural areas in the State.

(6) MANNER OF PROVIDING SERVICES.—With respect to the provision of early intervention services for HIV disease to an individual, a funding agreement for a grant under section 1921 for a designated State is that—

(A) such services will be undertaken voluntarily by, and with the informed consent of, the individual; and

(B) undergoing such services will not be required as a condition of receiving treatment services for substance abuse or any other services.

(7) DEFINITIONS.—For purposes of this subsection:

(A) The term “designated State” means a State described in paragraph (2).

(B) The term “early intervention services”, with respect to HIV disease, means—

(i) appropriate pretest counseling;

(ii) testing individuals with respect to such disease, including tests to confirm the presence of the disease, tests to diagnose the extent of the deficiency in the immune system, and tests to provide information on appropriate therapeutic measures for preventing and treating the deterioration of the immune system and for preventing and treating conditions arising from the disease;

(iii) appropriate post-test counseling; and

(iv) providing the therapeutic measures described in clause (ii).

(C) The term “HIV disease” means infection with the etiologic agent for acquired immune deficiency syndrome.

(c) EXPENDITURE OF GRANT FOR COMPLIANCE WITH AGREEMENTS.—

(1) IN GENERAL.—A grant under section 1921 may be expended for purposes of compliance with the agreements required in this section, subject to paragraph (2).

(2) LIMITATION.—A funding agreement for a grant under section 1921 for a State is that the grant will not be expended to make payment for any service provided for purposes of compliance with this section to the extent that payment has been made, or can reasonably be expected to be made, with respect to such service—

(A) under any State compensation program, under any insurance policy, or under any Federal or State health benefits program (including the program established in title XVIII of the Social Security Act and the program established in title XIX of such Act); or

(B) by an entity that provides health services on a prepaid basis.

(d) MAINTENANCE OF EFFORT.—With respect to services provided for by a State for purposes of compliance with this section, a funding agreement for a grant under section 1921 is that the State will maintain expenditures of non-Federal amounts for such services at a level that is not less than average level of such expenditures maintained by the State for 2-year period preceding the first fiscal year for which the State receives such a grant.

(e) APPLICABILITY OF CERTAIN PROVISION.—Section 1931 applies to this section (and to each other provision of this subpart).

SEC. 1925. [300x-25] GROUP HOMES FOR RECOVERING SUBSTANCE ABUSERS.

(a) STATE REVOLVING FUNDS FOR ESTABLISHMENT OF HOMES.—For fiscal year 1993 and subsequent fiscal years, the Secretary may make a grant under section 1921 only if the State involved has established, and is providing for the ongoing operation of, a revolving fund as follows:

(1) The purpose of the fund is to make loans for the costs of establishing programs for the provision of housing in which individuals recovering from alcohol or drug abuse may reside in groups of not less than 6 individuals. The fund is established directly by the State or through the provision of a grant or contract to a nonprofit private entity.

(2) The programs are carried out in accordance with guidelines issued under subsection (b).

(3) Not less than \$100,000 is available for the fund.

(4) Loans made from the revolving fund do not exceed \$4,000 and each such loan is repaid to the revolving fund by the residents of the housing involved not later than 2 years after the date on which the loan is made.

(5) Each such loan is repaid by such residents through monthly installments, and a reasonable penalty is assessed for each failure to pay such periodic installments by the date specified in the loan agreement involved.

(6) Such loans are made only to nonprofit private entities agreeing that, in the operation of the program established pursuant to the loan—

(A) the use of alcohol or any illegal drug in the housing provided by the program will be prohibited;

(B) any resident of the housing who violates such prohibition will be expelled from the housing;

(C) the costs of the housing, including fees for rent and utilities, will be paid by the residents of the housing; and

(D) the residents of the housing will, through a majority vote of the residents, otherwise establish policies governing residence in the housing, including the manner in which applications for residence in the housing are approved.

(b) **ISSUANCE BY SECRETARY OF GUIDELINES.**—The Secretary shall ensure that there are in effect guidelines under this subpart for the operation of programs described in subsection (a).

(c) **APPLICABILITY TO TERRITORIES.**—The requirements established in subsection (a) shall not apply to any territory of the United States other than the Commonwealth of Puerto Rico.

SEC. 1926. [300x-26] STATE LAW REGARDING SALE OF TOBACCO PRODUCTS TO INDIVIDUALS UNDER AGE OF 18.

(a) **RELEVANT LAW.**—

(1) **IN GENERAL.**—Subject to paragraph (2), for fiscal year 1994 and subsequent fiscal years, the Secretary may make a grant under section 1921 only if the State involved has in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18.

(2) **DELAYED APPLICABILITY FOR CERTAIN STATES.**—In the case of a State whose legislature does not convene a regular session in fiscal year 1993, and in the case of a State whose legislature does not convene a regular session in fiscal year 1994, the requirement described in paragraph (1) as a condition of a receipt of a grant under section 1921 shall apply only for fiscal year 1995 and subsequent fiscal years.

(b) **ENFORCEMENT.**—

(1) **IN GENERAL.**—For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant under section 1921 is that the State involved will enforce the law described in subsection (a) in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18.

(2) **ACTIVITIES AND REPORTS REGARDING ENFORCEMENT.**—For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant under section 1921 is that the State involved will—

(A) annually conduct random, unannounced inspections to ensure compliance with the law described in subsection (a); and

(B) annually submit to the Secretary a report describing—

(i) the activities carried out by the State to enforce such law during the fiscal year preceding the fiscal year for which the State is seeking the grant;

(ii) the extent of success the State has achieved in reducing the availability of tobacco products to individuals under the age of 18; and

(iii) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

(c) **NONCOMPLIANCE OF STATE.**—Before making a grant under section 1921 to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether the State has maintained compliance with subsections (a) and (b). If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under such section for the State for the fiscal year involved by an amount equal to—

(1) in the case of the first applicable fiscal year, 10 percent of the amount determined under section 1933 for the State for the fiscal year;

(2) in the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 1933 for the State for the fiscal year;

(3) in the case of the second such fiscal year, 30 percent of the amount determined under section 1933 for the State for the fiscal year; and

(4) in the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 1933 for the State for the fiscal year.

(d) **DEFINITION.**—For purposes of this section, the term “first applicable fiscal year” means—

(1) fiscal year 1995, in the case of any State described in subsection (a)(2); and

(2) fiscal year 1994, in the case of any other State.

SEC. 1927. [300x-27] TREATMENT SERVICES FOR PREGNANT WOMEN.

(a) **IN GENERAL.**—A funding agreement for a grant under section 1921 is that the State involved—

(1) will ensure that each pregnant woman in the State who seeks or is referred for and would benefit from such services is given preference in admissions to treatment facilities receiving funds pursuant to the grant; and

(2) will, in carrying out paragraph (1), publicize the availability to such women of services from the facilities and the fact that the women receive such preference.

(b) **REFERRALS REGARDING STATES.**—A funding agreement for a grant under section 1921 is that, in carrying out subsection (a)(1)—

(1) the State involved will require that, in the event that a treatment facility has insufficient capacity to provide treatment services to any woman described in such subsection who seeks the services from the facility, the facility refer the woman to the State; and

(2) the State, in the case of each woman for whom a referral under paragraph (1) is made to the State—

(A) will refer the woman to a treatment facility that has the capacity to provide treatment services to the woman; or

(B) will, if no treatment facility has the capacity to admit the woman, make interim services available to the woman not later than 48 hours after the woman seeks the treatment services.

SEC. 1928. [300x-28] ADDITIONAL AGREEMENTS.

(a) **IMPROVEMENT OF PROCESS FOR APPROPRIATE REFERRALS FOR TREATMENT.**—With respect to individuals seeking treatment services, a funding agreement for a grant under section 1921 is that the State involved will improve (relative to fiscal year 1992) the process in the State for referring the individuals to treatment facilities that can provide to the individuals the treatment modality that is most appropriate for the individuals.

(b) **CONTINUING EDUCATION.**—With respect to any facility for treatment services or prevention activities that is receiving amounts from a grant under section 1921, a funding agreement for a State for a grant under such section is that continuing education in such services or activities (or both, as the case may be) will be made available to employees of the facility who provide the services or activities.

(c) **COORDINATION OF VARIOUS ACTIVITIES AND SERVICES.**—A funding agreement for a grant under section 1921 is that the State involved will coordinate prevention and treatment activities with the provision of other appropriate services (including health, social, correctional and criminal justice, educational, vocational rehabilitation, and employment services).

(d) **WAIVER OF REQUIREMENT.**—

(1) **IN GENERAL.**—Upon the request of a State, the Secretary may provide to a State a waiver of any or all of the requirements established in this section if the Secretary determines that, with respect to services for the prevention and treatment of substance abuse, the requirement involved is unnecessary for maintaining quality in the provision of such services in the State.

(2) **DATE CERTAIN FOR ACTING UPON REQUEST.**—The Secretary shall approve or deny a request for a waiver under paragraph (1) not later than 120 days after the date on which the request is made.

(3) **APPLICABILITY OF WAIVER.**—Any waiver provided by the Secretary under paragraph (1) shall be applicable only to the fiscal year involved.

SEC. 1929. [300x-29] SUBMISSION TO SECRETARY OF STATEWIDE ASSESSMENT OF NEEDS.

The Secretary may make a grant under section 1921 only if the State submits to the Secretary an assessment of the need in the State for authorized activities (which assessment is conducted in accordance with criteria issued by the Secretary), both by locality and by the State in general, which assessment includes a description of—

(1) the incidence and prevalence in the State of drug abuse and the incidence and prevalence in the State of alcohol abuse and alcoholism;

(2) current prevention and treatment activities in the State;

(3) the need of the State for technical assistance to carry out such activities;

(4) efforts by the State to improve such activities; and

(5) the extent to which the availability of such activities is insufficient to meet the need for the activities, the interim services to be made available under sections 1923(a) and 1927(b), and the manner in which such services are to be so available.

SEC. 1930. [300x-30] MAINTENANCE OF EFFORT REGARDING STATE EXPENDITURES.

(a) **IN GENERAL.**—With respect to the principal agency of a State for carrying out authorized activities, a funding agreement for a grant under section 1921 for the State for a fiscal year is that such agency will for such year maintain aggregate State expenditures for authorized activities at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying for the grant.

(b) **WAIVER.**—

(1) **IN GENERAL.**—Upon the request of a State, the Secretary may waive all or part of the requirement established in subsection (a) if the Secretary determines that extraordinary economic conditions in the State justify the waiver.

(2) **DATE CERTAIN FOR ACTING UPON REQUEST.**—The Secretary shall approve or deny a request for a waiver under paragraph (1) not later than 120 days after the date on which the request is made.

(3) **APPLICABILITY OF WAIVER.**—Any waiver provided by the Secretary under paragraph (1) shall be applicable only to the fiscal year involved.

(c) **NONCOMPLIANCE BY STATE.**—

(1) **IN GENERAL.**—In making a grant under section 1921 to a State for a fiscal year, the Secretary shall make a determination of whether, for the previous fiscal year, the State maintained material compliance with any agreement made under subsection (a). If the Secretary determines that a State has failed to maintain such compliance, the Secretary shall reduce the amount of the allotment under section 1921 for the State for the fiscal year for which the grant is being made by an amount equal to the amount constituting such failure for the previous fiscal year.

(2) **SUBMISSION OF INFORMATION TO SECRETARY.**—The Secretary may make a grant under section 1921 for a fiscal year only if the State involved submits to the Secretary information sufficient for the Secretary to make the determination required in paragraph (1).

SEC. 1931. [300x-31] RESTRICTIONS ON EXPENDITURE OF GRANT.

(a) **IN GENERAL.**—

(1) CERTAIN RESTRICTIONS.—A funding agreement for a grant under section 1921 is that the State involved will not expend the grant—

(A) to provide inpatient hospital services, except as provided in subsection (b);

(B) to make cash payments to intended recipients of health services;

(C) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(D) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds;

(E) to provide financial assistance to any entity other than a public or nonprofit private entity; or

(F) to carry out any program prohibited by section 256(b) of the Health Omnibus Programs Extension of 1988 (42 U.S.C. 300ee-5).

(2) LIMITATION ON ADMINISTRATIVE EXPENSES.—A funding agreement for a grant under section 1921 is that the State involved will not expend more than 5 percent of the grant to pay the costs of administering the grant.

(3) LIMITATION REGARDING PENAL AND CORRECTIONAL INSTITUTIONS.—A funding agreement for a State for a grant under section 1921 is that, in expending the grant for the purpose of providing treatment services in penal or correctional institutions of the State, the State will not expend more than an amount equal to the amount expended for such purpose by the State from the grant made under section 1912A to the State for fiscal year 1991 (as section 1912A was in effect for such fiscal year).

(b) EXCEPTION REGARDING INPATIENT HOSPITAL SERVICES.—

(1) MEDICAL NECESSITY AS PRECONDITION.—With respect to compliance with the agreement made under subsection (a), a State may expend a grant under section 1921 to provide inpatient hospital services as treatment for substance abuse only if it has been determined, in accordance with guidelines issued by the Secretary, that such treatment is a medical necessity for the individual involved, and that the individual cannot be effectively treated in a community-based, nonhospital, residential program of treatment.

(2) RATE OF PAYMENT.—In the case of an individual for whom a grant under section 1921 is expended to provide inpatient hospital services described in paragraph (1), a funding agreement for the grant for the State involved is that the daily rate of payment provided to the hospital for providing the services to the individual will not exceed the comparable daily rate provided for community-based, nonhospital, residential programs of treatment for substance abuse.

(c) WAIVER REGARDING CONSTRUCTION OF FACILITIES.—

(1) IN GENERAL.—The Secretary may provide to any State a waiver of the restriction established in subsection (a)(1)(C) for the purpose of authorizing the State to expend a grant

under section 1921 for the construction of a new facility or rehabilitation of an existing facility, but not for land acquisition.

(2) STANDARD REGARDING NEED FOR WAIVER.—The Secretary may approve a waiver under paragraph (1) only if the State demonstrates to the Secretary that adequate treatment cannot be provided through the use of existing facilities and that alternative facilities in existing suitable buildings are not available.

(3) AMOUNT.—In granting a waiver under paragraph (1), the Secretary shall allow the use of a specified amount of funds to construct or rehabilitate a specified number of beds for residential treatment and a specified number of slots for outpatient treatment, based on reasonable estimates by the State of the costs of construction or rehabilitation. In considering waiver applications, the Secretary shall ensure that the State has carefully designed a program that will minimize the costs of additional beds.

(4) MATCHING FUNDS.—The Secretary may grant a waiver under paragraph (1) only if the State agrees, with respect to the costs to be incurred by the State in carrying out the purpose of the waiver, to make available non-Federal contributions in cash toward such costs in an amount equal to not less than \$1 for each \$1 of Federal funds provided under section 1921.

(5) DATE CERTAIN FOR ACTING UPON REQUEST.—The Secretary shall act upon a request for a waiver under paragraph (1) not later than 120 days after the date on which the request is made.

SEC. 1932. [300x-32] APPLICATION FOR GRANT; APPROVAL OF STATE PLAN.

(a) IN GENERAL.—For purposes of section 1921, an application for a grant under such section for a fiscal year is in accordance with this section if, subject to subsections (c) and (d)(2)—

(1) the State involved submits the application not later than the date specified by the Secretary;

(2) the application contains each funding agreement that is described in this subpart or subpart III for such a grant (other than any such agreement that is not applicable to the State);

(3) the agreements are made through certification from the chief executive officer of the State;

(4) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary;

(5) the application contains the information required in section 1929, the information required in section 1930(c)(2), and the report required in section 1942(a);

(6)(A) the application contains a plan in accordance with subsection (b) and the plan is approved by the Secretary; and

(B) the State provides assurances satisfactory to the Secretary that the State complied with the provisions of the plan under subparagraph (A) that was approved by the Secretary for the most recent fiscal year for which the State received a grant under section 1921; and

(7) the application (including the plan under paragraph (6)) is otherwise in such form, is made in such manner, and

contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this subpart. (b) STATE PLAN.—

(1) IN GENERAL.—A plan submitted by a State under subsection (a)(6) is in accordance with this subsection if the plan contains detailed provisions for complying with each funding agreement for a grant under section 1921 that is applicable to the State, including a description of the manner in which the State intends to expend the grant.

(2) AUTHORITY OF SECRETARY REGARDING MODIFICATIONS.—As a condition of making a grant under section 1921 to a State for a fiscal year, the Secretary may require that the State modify any provision of the plan submitted by the State under subsection (a)(6) (including provisions on priorities in carrying out authorized activities). If the Secretary approves the plan and makes the grant to the State for the fiscal year, the Secretary may not during such year require the State to modify the plan.

(3) AUTHORITY OF CENTER FOR SUBSTANCE ABUSE PREVENTION.—With respect to plans submitted by the States under subsection (a)(6), the Secretary, acting through the Director of the Center for Substance Abuse Prevention, shall review and approve or disapprove the provisions of the plans that relate to prevention activities.

(c) WAIVERS REGARDING CERTAIN TERRITORIES.—In the case of any territory of the United States whose allotment under section 1921 for the fiscal year is the amount specified in section 1933(c)(2)(B), the Secretary may waive such provisions of this subpart and subpart III as the Secretary determines to be appropriate, other than the provisions of section 1931.

(d) ISSUANCE OF REGULATIONS; PRECONDITION TO MAKING GRANTS.—

(1) REGULATIONS.—Not later than August 25, 1992, the Secretary, acting as appropriate through the Director of the Center for Treatment Improvement or the Director of the Center for Substance Abuse Prevention, shall by regulation establish standards specifying the circumstances in which the Secretary will consider an application for a grant under section 1921 to be in accordance with this section.

(2) ISSUANCE AS PRECONDITION TO MAKING GRANTS.—The Secretary may not make payments under any grant under section 1921 for fiscal year 1993 on or after January 1, 1993, unless the Secretary has issued standards under paragraph (1).

SEC. 1933. [300x-33] DETERMINATION OF AMOUNT OF ALLOTMENT.

(a) STATES.—

(1) IN GENERAL.—Subject to subsection (b), the Secretary shall determine the amount of the allotment required in section 1921 for a State for a fiscal year as follows:

(A) The formula established in paragraph (1) of section 1918(a) shall apply to this subsection to the same extent and in the same manner as the formula applies for purposes of section 1918(a), except that, in the application of such formula for purposes of this subsection, the modifications described in subparagraph (B) shall apply.

(B) For purposes of subparagraph (A), the modifications described in this subparagraph are as follows:

(i) The amount specified in paragraph (2)(A) of section 1918(a) is deemed to be the amount appropriated under section 1935(a) for allotments under section 1921 for the fiscal year involved.

(ii) The term "P" is deemed to have the meaning given in paragraph (2) of this subsection. Section 1918(a)(5)(B) applies to the data used in determining such term for the States.

(iii) The factor determined under paragraph (8) of section 1918(a) is deemed to have the purpose of reflecting the differences that exist between the State involved and other States in the costs of providing authorized services.

(2) DETERMINATION OF TERM "P".—For purposes of this subsection, the term "P" means the percentage that is the arithmetic mean of the percentage determined under subparagraph (A) and the percentage determined under subparagraph (B), as follows:

(A) The percentage constituted by the ratio of—

(i) an amount equal to the sum of the total number of individuals who reside in the State involved and are between 18 and 24 years of age (inclusive) and the number of individuals in the State who reside in urbanized areas of the State and are between such years of age; to

(ii) an amount equal to the total of the respective sums determined for the States under clause (i).

(B) The percentage constituted by the ratio of—

(i) the total number of individuals in the State who are between 25 and 64 years of age (inclusive); to

(ii) an amount equal to the sum of the respective amounts determined for the States under clause (i).

(b) MINIMUM ALLOTMENTS FOR STATES.—For each of the fiscal years 1993 and 1994, the amount of the allotment required in section 1921 for a State for the fiscal year involved shall be the greater of—

(1) the amount determined under subsection (a) for the State for the fiscal year; and

(2) an amount equal to 79.4 percent of the amount received by the State from allotments made pursuant to this part for fiscal year 1992 (including reallotments under section 205(a) of the ADAMHA Reorganization Act).

(c) TERRITORIES.—

(1) DETERMINATION UNDER FORMULA.—Subject to paragraphs (2) and (4), the amount of an allotment under section 1921 for a territory of the United States for a fiscal year shall be the product of—

(A) an amount equal to the amounts reserved under paragraph (3) for the fiscal year; and

(B) a percentage equal to the quotient of—

(i) the civilian population of the territory, as indicated by the most recently available data; divided by

(ii) the aggregate civilian population of the territories of the United States, as indicated by such data.

(2) MINIMUM ALLOTMENT FOR TERRITORIES.—The amount of an allotment under section 1921 for a territory of the United States for a fiscal year shall be the greater of—

(A) the amount determined under paragraph (1) for the territory for the fiscal year;

(B) \$50,000; and

(C) with respect to fiscal years 1993 and 1994, an amount equal to 79.4 percent of the amount received by the territory from allotments made pursuant to this part for fiscal year 1992.

(3) RESERVATION OF AMOUNTS.—The Secretary shall each fiscal year reserve for the territories of the United States 1.5 percent of the amounts appropriated under section 1935(a) for allotments under section 1921 for the fiscal year.

(4) AVAILABILITY OF DATA ON POPULATION.—With respect to data on the civilian population of the territories of the United States, if the Secretary determines for a fiscal year that recent such data for purposes of paragraph (1)(B) do not exist regarding a territory, the Secretary shall for such purposes estimate the civilian population of the territory by modifying the data on the territory to reflect the average extent of change occurring during the ensuing period in the population of all territories with respect to which recent such data do exist.

(5) APPLICABILITY OF CERTAIN PROVISIONS.—For purposes of subsections (a) and (b), the term "State" does not include the territories of the United States.

(d) INDIAN TRIBES AND TRIBAL ORGANIZATIONS.—

(1) IN GENERAL.—If the Secretary—

(A) receives a request from the governing body of an Indian tribe or tribal organization within any State that funds under this subpart be provided directly by the Secretary to such tribe or organization; and

(B) makes a determination that the members of such tribe or tribal organization would be better served by means of grants made directly by the Secretary under this; the Secretary shall reserve from the allotment under section 1921 for the State for the fiscal year involved an amount that bears the same ratio to the allotment as the amount provided under this subpart to the tribe or tribal organization for fiscal year 1991 for activities relating to the prevention and treatment of the abuse of alcohol and other drugs bore to the amount of the portion of the allotment under this subpart for the State for such fiscal year that was expended for such activities.

(2) TRIBE OR TRIBAL ORGANIZATION AS GRANTEE.—The amount reserved by the Secretary on the basis of a determination under this paragraph shall be granted to the Indian tribe or tribal organization serving the individuals for whom such a determination has been made.

(3) APPLICATION.—In order for an Indian tribe or tribal organization to be eligible for a grant for a fiscal year under this paragraph, it shall submit to the Secretary a plan for such fis-

cal year that meets such criteria as the Secretary may prescribe.

(4) DEFINITION.—The terms “Indian tribe” and “tribal organization” have the same meaning given such terms in subsections (b) and (c) of section 4 of the Indian Self-Determination and Education Assistance Act.

SEC. 1934. [300x-34] DEFINITIONS.

For purposes of this subpart:

(1) The term “authorized activities”, subject to section 1931, means the activities described in section 1921(b).

(2) The term “funding agreement”, with respect to a grant under section 1921 to a State, means that the Secretary may make such a grant only if the State makes the agreement involved.

(3) The term “prevention activities”, subject to section 1931, means activities to prevent substance abuse.

(4) The term “substance abuse” means the abuse of alcohol or other drugs.

(5) The term “treatment activities” means treatment services and, subject to section 1931, authorized activities that are related to treatment services.

(6) The term “treatment facility” means an entity that provides treatment services.

(7) The term “treatment services”, subject to section 1931, means treatment for substance abuse.

SEC. 1935. [300x-35] FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, subpart III and section 505 with respect to substance abuse, and section 515(d), there are authorized to be appropriated \$1,500,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(b) ALLOCATIONS FOR TECHNICAL ASSISTANCE, NATIONAL DATA BASE, DATA COLLECTION, AND PROGRAM EVALUATIONS.—

(1) IN GENERAL.—

(A) For the purpose of carrying out section 1948(a) with respect to substance abuse, section 515(d), and the purposes specified in subparagraphs (B) and (C), the Secretary shall obligate 5 percent of the amounts appropriated under subsection (a) each fiscal year.

(B) The purpose specified in this subparagraph is the collection of data in this paragraph is carrying out section 505 with respect to substance abuse.

(C) The purpose specified in this subparagraph is the conduct of evaluations of authorized activities to determine methods for improving the availability and quality of such activities.

(2) ACTIVITIES OF CENTER FOR SUBSTANCE ABUSE PREVENTION.—Of the amounts reserved under paragraph (1) for a fiscal year, the Secretary, acting through the Director of the Center for Substance Abuse Prevention, shall obligate 20 percent for carrying out paragraph (1)(C), section 1949(a) with respect to prevention activities, and section 515(d).

Subpart III—General Provisions

SEC. 1941. [300x-51] OPPORTUNITY FOR PUBLIC COMMENT ON STATE PLANS.

A funding agreement for a grant under section 1911 or 1921 is that the State involved will make the plan required in section 1912, and the plan required in section 1932, respectively, public within the State in such manner as to facilitate comment from any person (including any Federal or other public agency) during the development of the plan (including any revisions) and after the submission of the plan to the Secretary.

SEC. 1942. [300x-52] REQUIREMENT OF REPORTS AND AUDITS BY STATES.

(a) REPORT.—A funding agreement for a grant under section 1911 or 1921 is that the State involved will submit to the Secretary a report in such form and containing such information as the Secretary determines (after consultation with the States and the Comptroller General) to be necessary for securing a record and a description of—

(1) the purposes for which the grant received by the State for the preceding fiscal year under the program involved were expended and a description of the activities of the State under the program; and

(2) the recipients of amounts provided in the grant.

(b) AUDITS.—A funding agreement for a grant under section 1911 or 1921 is that the State will, with respect to the grant, comply with chapter 75 of title 31, United States Code.

(c) AVAILABILITY TO PUBLIC.—A funding agreement for a grant under section 1911 or 1921 is that the State involved will—

(1) make copies of the reports and audits described in this section available for public inspection within the State; and

(2) provide copies of the report under subsection (a), upon request, to any interested person (including any public agency).

SEC. 1943. [300x-53] ADDITIONAL REQUIREMENTS.

(a) IN GENERAL.—A funding agreement for a grant under section 1911 or 1921 is that the State involved will—

(1)(A) for the fiscal year for which the grant involved is provided, provide for independent peer review to assess the quality, appropriateness, and efficacy of treatment services provided in the State to individuals under the program involved; and

(B) ensure that, in the conduct of such peer review, not fewer than 5 percent of the entities providing services in the State under such program are reviewed (which 5 percent is representative of the total population of such entities);

(2) permit and cooperate with Federal investigations undertaken in accordance with section 1945; and

(3) provide to the Secretary any data required by the Secretary pursuant to section 505 and will cooperate with the Secretary in the development of uniform criteria for the collection of data pursuant to such section.

(b) PATIENT RECORDS.—The Secretary may make a grant under section 1911 or 1921 only if the State involved has in effect a sys-

tem to protect from inappropriate disclosure patient records maintained by the State in connection with an activity funded under the program involved or by any entity which is receiving amounts from the grant.

SEC. 1944. [300x-54] DISPOSITION OF CERTAIN FUNDS APPROPRIATED FOR ALLOTMENTS.

(a) **IN GENERAL.**—Amounts described in subsection (b) and available for a fiscal year pursuant to section 1911 or 1921, as the case may be, shall be allotted by the Secretary and paid to the States receiving a grant under the program involved, other than any State referred to in subsection (b) with respect to such program. Such amounts shall be allotted in a manner equivalent to the manner in which the allotment under the program involved was determined.

(b) **SPECIFICATION OF AMOUNTS.**—The amounts referred to in subsection (a) are any amounts that—

(1) are not paid to States under the program involved as a result of—

(A) the failure of any State to submit an application in accordance with the program;

(B) the failure of any State to prepare such application in compliance with the program; or

(C) any State informing the Secretary that the State does not intend to expend the full amount of the allotment made to the State under the program;

(2) are terminated, repaid, or offset under section 1945;

(3) in the case of the program established in section 1911, are available as a result of reductions in allotments under such section pursuant to section 1912(d) or 1915(b); or

(4) in the case of the program established in section 1921, are available as a result of reductions in allotments under such section pursuant to section 1926 or 1930.

SEC. 1945. [300x-55] FAILURE TO COMPLY WITH AGREEMENTS.

(a) **SUSPENSION OR TERMINATION OF PAYMENTS.**—Subject to subsection (e), if the Secretary determines that a State has materially failed to comply with the agreements or other conditions required for the receipt of a grant under the program involved, the Secretary may in whole or in part suspend payments under the grant, terminate the grant for cause, or employ such other remedies (including the remedies provided for in subsections (b) and (c)) as may be legally available and appropriate in the circumstances involved.

(b) **REPAYMENT OF PAYMENTS.**—

(1) **IN GENERAL.**—Subject to subsection (e), the Secretary may require a State to repay with interest any payments received by the State under section 1911 or 1921 that the Secretary determines were not expended by the State in accordance with the agreements required under the program involved.

(2) **OFFSET AGAINST PAYMENTS.**—If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against the amount of any payment due to be paid to the State under the program involved.

(c) WITHHOLDING OF PAYMENTS.—

(1) IN GENERAL.—Subject to subsections (e) and (g)(3), the Secretary may withhold payments due under section 1911 or 1921 if the Secretary determines that the State involved is not expending amounts received under the program involved in accordance with the agreements required under the program.

(2) TERMINATION OF WITHHOLDING.—The Secretary shall cease withholding payments from a State under paragraph (1) if the Secretary determines that there are reasonable assurances that the State will expend amounts received under the program involved in accordance with the agreements required under the program.

(d) APPLICABILITY OF REMEDIES TO CERTAIN VIOLATIONS.—

(1) IN GENERAL.—With respect to agreements or other conditions for receiving a grant under the program involved, in the case of the failure of a State to maintain material compliance with a condition referred to in paragraph (2), the provisions for noncompliance with the condition that are provided in the section establishing the condition shall apply in lieu of subsections (a) through (c) of this section.

(2) RELEVANT CONDITIONS.—For purposes of paragraph (1):

(A) In the case of the program established in section 1911, a condition referred to in this paragraph is the condition established in section 1912(d) and the condition established in section 1915(b).

(B) In the case of the program established in section 1921, a condition referred to in this paragraph is the condition established in section 1926 and the condition established in section 1930.

(e) OPPORTUNITY FOR HEARING.—Before taking action against a State under any of subsections (a) through (c) (or under a section referred to in subsection (d)(2), as the case may be), the Secretary shall provide to the State involved adequate notice and an opportunity for a hearing.

(f) REQUIREMENT OF HEARING IN CERTAIN CIRCUMSTANCES.—

(1) IN GENERAL.—If the Secretary receives a complaint that a State has failed to maintain material compliance with the agreements or other conditions required for receiving a grant under the program involved (including any condition referred to for purposes of subsection (d)), and there appears to be reasonable evidence to support the complaint, the Secretary shall promptly conduct a hearing with respect to the complaint.

(2) FINDING OF MATERIAL NONCOMPLIANCE.—If in a hearing under paragraph (1) the Secretary finds that the State involved has failed to maintain material compliance with the agreement or other condition involved, the Secretary shall take such action under this section as may be appropriate to ensure that material compliance is so maintained, or such action as may be required in a section referred to in subsection (d)(2), as the case may be.

(g) CERTAIN INVESTIGATIONS.—

(1) REQUIREMENT REGARDING SECRETARY.—The Secretary shall in fiscal year 1994 and each subsequent fiscal year conduct in not less than 10 States investigations of the expendi-

ture of grants received by the States under section 1911 or 1921 in order to evaluate compliance with the agreements required under the program involved.

(2) **PROVISION OF RECORDS ETC. UPON REQUEST.**—Each State receiving a grant under section 1911 or 1921, and each entity receiving funds from the grant, shall make appropriate books, documents, papers, and records available to the Secretary or the Comptroller General, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefor.

(3) **LIMITATIONS ON AUTHORITY.**—The Secretary may not institute proceedings under subsection (c) unless the Secretary has conducted an investigation concerning whether the State has expended payments under the program involved in accordance with the agreements required under the program. Any such investigation shall be conducted within the State by qualified investigators.

SEC. 1946. [300x-56] PROHIBITIONS REGARDING RECEIPT OF FUNDS.

(a) **ESTABLISHMENT.**—

(1) **CERTAIN FALSE STATEMENTS AND REPRESENTATIONS.**—A person shall not knowingly and willfully make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which payments may be made by a State from a grant made to the State under section 1911 or 1921.

(2) **CONCEALING OR FAILING TO DISCLOSE CERTAIN EVENTS.**—A person with knowledge of the occurrence of any event affecting the initial or continued right of the person to receive any payments from a grant made to a State under section 1911 or 1921 shall not conceal or fail to disclose any such event with an intent fraudulently to secure such payment either in a greater amount than is due or when no such amount is due.

(b) **CRIMINAL PENALTY FOR VIOLATION OF PROHIBITION.**—Any person who violates any prohibition established in subsection (a) shall for each violation be fined in accordance with title 18, United States Code, or imprisoned for not more than 5 years, or both.

SEC. 1947. [300x-57] NONDISCRIMINATION.

(a) **IN GENERAL.**—

(1) **RULE OF CONSTRUCTION REGARDING CERTAIN CIVIL RIGHTS LAWS.**—For the purpose of applying the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975, on the basis of handicap under section 504 of the Rehabilitation Act of 1973, on the basis of sex under title IX of the Education Amendments of 1972, or on the basis of race, color, or national origin under title VI of the Civil Rights Act of 1964, programs and activities funded in whole or in part with funds made available under section 1911 or 1921 shall be considered to be programs and activities receiving Federal financial assistance.

(2) **PROHIBITION.**—No person shall on the ground of sex (including, in the case of a woman, on the ground that the

woman is pregnant), or on the ground of religion, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity funded in whole or in part with funds made available under section 1911 or 1921.

(b) ENFORCEMENT.—

(1) REFERRALS TO ATTORNEY GENERAL AFTER NOTICE.—Whenever the Secretary finds that a State, or an entity that has received a payment pursuant to section 1911 or 1921, has failed to comply with a provision of law referred to in subsection (a)(1), with subsection (a)(2), or with an applicable regulation (including one prescribed to carry out subsection (a)(2)), the Secretary shall notify the chief executive officer of the State and shall request the chief executive officer to secure compliance. If within a reasonable period of time, not to exceed 60 days, the chief executive officer fails or refuses to secure compliance, the Secretary may—

(A) refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted;

(B) exercise the powers and functions provided by the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, title IX of the Education Amendments of 1972, or title VI of the Civil Rights Act of 1964, as may be applicable; or

(C) take such other actions as may be authorized by law.

(2) AUTHORITY OF ATTORNEY GENERAL.—When a matter is referred to the Attorney General pursuant to paragraph (1)(A), or whenever the Attorney General has reason to believe that a State or an entity is engaged in a pattern or practice in violation of a provision of law referred to in subsection (a)(1) or in violation of subsection (a)(2), the Attorney General may bring a civil action in any appropriate district court of the United States for such relief as may be appropriate, including injunctive relief.

SEC. 1948. [300x-58] TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) TECHNICAL ASSISTANCE.—The Secretary shall, without charge to a State receiving a grant under section 1911 or 1921, provide to the State (or to any public or nonprofit private entity within the State) technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to the program involved. The Secretary may provide such technical assistance directly, through contract, or through grants.

(b) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) IN GENERAL.—Upon the request of a State receiving a grant under section 1911 or 1921, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out the program involved and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) **CORRESPONDING REDUCTION IN PAYMENTS.**—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the program involved to the State by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 1949. [300x-59] REPORT BY SECRETARY.

Not later than January 24, 1994, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report on the activities of the States carried out pursuant to the programs established in sections 1911 and 1921. Such report may include any recommendations of the Secretary for appropriate changes in legislation.

SEC. 1950. [300x-60] RULE OF CONSTRUCTION REGARDING DELEGATION OF AUTHORITY TO STATES.

With respect to States receiving grants under section 1911 or 1921, this part may not be construed to authorize the Secretary to delegate to the States the primary responsibility for interpreting the governing provisions of this part.

SEC. 1951. [300x-61] SOLICITATION OF VIEWS OF CERTAIN ENTITIES.

In carrying out this part, the Secretary, as appropriate, shall solicit the views of the States and other appropriate entities.

SEC. 1952. [300x-62] AVAILABILITY TO STATES OF GRANT PAYMENTS.

(a) **IN GENERAL.**—Subject to subsection (b), any amounts paid to a State under the program involved shall be available for obligation until the end of the fiscal year for which the amounts were paid, and if obligated by the end of such year, shall remain available for expenditure until the end of the succeeding fiscal year.

(b) **EXCEPTION REGARDING NONCOMPLIANCE OF SUBGRANTEES.**—If a State has in accordance with subsection (a) obligated amounts paid to the State under the program involved, in any case in which the Secretary determines that the obligation consists of a grant or contract awarded by the State, and that the State has terminated or reduced the amount of such financial assistance on the basis of the failure of the recipient of the assistance to comply with the terms upon which the assistance was conditioned—

(1) the amounts involved shall be available for reobligation by the State through September 30 of the fiscal year following the fiscal year for which the amounts were paid to the State; and

(2) any of such amounts that are obligated by the State in accordance with paragraph (1) shall be available for expenditure through such date.

SEC. 1953. [300x-63] CONTINUATION OF CERTAIN PROGRAMS.

(a) **IN GENERAL.**—Of the amount allotted to the State of Hawaii under section 1911, and the amount allotted to such State under section 1921, an amount equal to the proportion of Native Hawaiians residing in the State to the total population of the State

shall be available, respectively, for carrying out the program involved for Native Hawaiians.

(b) **EXPENDITURE OF AMOUNTS.**—The amount made available under subsection (a) may be expended only through contracts entered into by the State of Hawaii with public and private nonprofit organizations to enable such organizations to plan, conduct, and administer comprehensive substance abuse and treatment programs for the benefit of Native Hawaiians. In entering into contracts under this section, the State of Hawaii shall give preference to Native Hawaiian organizations and Native Hawaiian health centers.

(c) **DEFINITIONS.**—For the purposes of this subsection, the terms “Native Hawaiian”, “Native Hawaiian organization”, and “Native Hawaiian health center” have the meaning given such terms in section 2308 of subtitle D of title II of the Anti-Drug Abuse Act of 1988.

SEC. 1954. [300x-64] DEFINITIONS.

(a) **DEFINITIONS FOR SUBPART III.**—For purposes of this subpart:

(1) The term “program involved” means the program of grants established in section 1911 or 1921, or both, as indicated by whether the State involved is receiving or is applying to receive a grant under section 1911 or 1921, or both.

(2)(A) The term “funding agreement”, with respect to a grant under section 1911, has the meaning given such term in section 1919.

(B) The term “funding agreement”, with respect to a grant under section 1921, has the meaning given such term in section 1934.

(b) **DEFINITIONS FOR PART B.**—For purposes of this part:

(1) The term “Comptroller General” means the Comptroller General of the United States.

(2) The term “State”, except as provided in sections 1918(c)(5) and 1933(c)(5), means each of the several States, the District of Columbia, and each of the territories of the United States.

(3) The term “territories of the United States” means each of the Commonwealth of Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Palau, the Marshall Islands, and Micronesia.

(4) The term “interim services”, in the case of an individual in need of treatment for substance abuse who has been denied admission to a program of such treatment on the basis of the lack of the capacity of the program to admit the individual, means services for reducing the adverse health effects of such abuse, for promoting the health of the individual, and for reducing the risk of transmission of disease, which services are provided until the individual is admitted to such a program.

PART C—CERTAIN PROGRAMS REGARDING SUBSTANCE ABUSE

Subpart I—Expansion of Capacity for Providing Treatment**SEC. 1971. [300y] CATEGORICAL GRANTS TO STATES.****(a) GRANTS FOR STATES WITH INSUFFICIENT CAPACITY.—**

(1) **IN GENERAL.**—The Secretary, acting through the Director of the Center for Substance Abuse Treatment, may make grants to States for the purpose of increasing the maximum number of individuals to whom public and nonprofit private entities in the States are capable of providing effective treatment for substance abuse.

(2) **ELIGIBLE STATES.**—The Director may not make a grant under subsection (a) to a State unless the number of individuals seeking treatment services in the State significantly exceeds the maximum number described in paragraph (1) that is applicable to the State.

(b) PRIORITY IN MAKING GRANTS.—

(1) **RESIDENTIAL TREATMENT SERVICES FOR PREGNANT WOMEN.**—In making grants under subsection (a), the Director shall give priority to States that agree to give priority in the expenditure of the grant to carrying out the purpose described in such subsection as the purpose relates to the provision of residential treatment services to pregnant women.

(2) **ADDITIONAL PRIORITY REGARDING MATCHING FUNDS.**—In the case of any application for a grant under subsection (a) that is receiving priority under paragraph (1), the Director shall give further priority to the application if the State involved agrees as a condition of receiving the grant to provide non-Federal contributions under subsection (c) in a greater amount than the amount required under such subsection for the applicable fiscal year.

(c) REQUIREMENT OF MATCHING FUNDS.—

(1) **IN GENERAL.**—Subject to paragraph (3), the Director may not make a grant under subsection (a) unless the State agrees, with respect to the costs of the program to be carried out by the State pursuant to such subsection, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is—

(A) for the first fiscal year for which the State receives such a grant, not less than \$1 for each \$9 of Federal funds provided in the grant;

(B) for any second or third such fiscal year, not less than \$1 for each \$9 of Federal funds provided in the grant; and

(C) for any subsequent such fiscal year, not less than \$1 for each \$3 of Federal funds provided in the grant.

(2) **DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.**—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Gov-

ernment, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(3) WAIVER.—The Director may waive the requirement established in paragraph (1) if the Director determines that extraordinary economic conditions in the State justify the waiver.

(d) LIMITATION REGARDING DIRECT TREATMENT SERVICES.—The Director may not make a grant under subsection (a) unless the State involved agrees that the grant will be expended only for the direct provision of treatment services. The preceding sentence may not be construed to authorize the expenditure of such a grant for the planning or evaluation of treatment services.

(e) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(f) DURATION OF GRANT.—The period during which payments are made to a State from a grant under subsection (a) may not exceed 5 years. The provision of such payments shall be subject to annual approval by the Director of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments.

(g) MAINTENANCE OF EFFORT.—The Director may not make a grant under subsection (a) unless the State involved agrees to maintain State expenditures for substance abuse treatment services at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the first fiscal year for which the State receives such a grant.

(h) RESTRICTIONS ON USE OF GRANT.—The Director may not make a grant under subsection (a) unless the State involved agrees that the grant will not be expended—

(1) to provide inpatient hospital services;

(2) to make cash payments to intended recipients of health services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(i) DEFINITIONS.—For purposes of this section—

(1) The term "Director" means the Director of the Center for Substance Abuse Treatment.

(2) The term "substance abuse" means the abuse of alcohol or other drugs.

(j) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$86,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

Subpart II—Interim Maintenance Treatment of Narcotics Dependence

SEC. 1976. [300y-11] INTERIM MAINTENANCE TREATMENT.

(a) REQUIREMENT REGARDING SECRETARY.—Subject to the following subsections of this section, for the purpose of reducing the incidence of the transmission of HIV disease pursuant to the intravenous abuse of heroin or other morphine-like drugs, the Secretary, in establishing conditions for the use of methadone in public or nonprofit private programs of treatment for dependence on such drugs, shall authorize such programs—

(1) to dispense methadone for treatment purposes to individuals who—

(A) meet the conditions for admission to such programs that dispense methadone as part of comprehensive treatment for such dependence; and

(B) are seeking admission to such programs that so dispense methadone, but as a result of the limited capacity of the programs, will not gain such admission until 14 or more days after seeking admission to the programs; and

(2) in dispensing methadone to such individuals, to provide only minimum ancillary services during the period in which the individuals are waiting for admission to programs of comprehensive treatment.

(b) INAPPLICABILITY OF REQUIREMENT IN CERTAIN CIRCUMSTANCES.—

(1) IN GENERAL.—The requirement established in subsection (a) for the Secretary does not apply if any or all of the following conditions are met:

(A) The preponderance of scientific research indicates that the risk of the transmission of HIV disease pursuant to the intravenous abuse of drugs is minimal.

(B) The preponderance of scientific research indicates that the medically supervised dispensing of methadone is not an effective method of reducing the extent of dependence on heroin and other morphine-like drugs.

(C) The preponderance of available data indicates that, of treatment programs that dispense methadone as part of comprehensive treatment, a substantial majority admit all individuals seeking services to the programs not later than 14 days after the individuals seek admission to the programs.

(2) EVALUATION BY SECRETARY.—In evaluating whether any or all of the conditions described in paragraph (1) have been met, the Secretary shall consult with the National Commission on Acquired Immune Deficiency Syndrome.

(c) CONDITIONS FOR OBTAINING AUTHORIZATION FROM SECRETARY.—

(1) IN GENERAL.—In carrying out the requirement established in subsection (a), the Secretary shall, after consultation with the National Commission on Acquired Immune Deficiency Syndrome, by regulation issue such conditions for treatment programs to obtain authorization from the Secretary to provide

interim maintenance treatment as may be necessary to carry out the purpose described in such subsection. Such conditions shall include conditions for preventing the unauthorized use of methadone.

(2) COUNSELING ON HIV DISEASE.—The regulations issued under paragraph (1) shall provide that an authorization described in such paragraph may not be issued to a treatment program unless the program provides to recipients of the treatment counseling on preventing exposure to and the transmission of HIV disease.

(3) PERMISSION OF RELEVANT STATE AS CONDITION OF AUTHORIZATION.—The regulations issued under paragraph (1) shall provide that the Secretary may not provide an authorization described in such paragraph to any treatment program in a State unless the chief public health officer of the State has certified to the Secretary that—

(A) such officer does not object to the provision of such authorizations to treatment programs in the State; and

(B) the provision of interim maintenance services in the State will not reduce the capacity of comprehensive treatment programs in the State to admit individuals to the programs (relative to the date on which such officer so certifies).

(4) DATE CERTAIN FOR ISSUANCE OF REGULATIONS; FAILURE OF SECRETARY.—The Secretary shall issue the final rule for purposes of the regulations required in paragraph (1), and such rule shall be effective, not later than the expiration of the 180-day period beginning on the date of the enactment of the ADAMHA Reorganization Act¹. If the Secretary fails to meet the requirement of the preceding sentence, the proposed rule issued on March 2, 1989, with respect to part 291 of title 21, Code of Federal Regulations (docket numbered 88N-0444; 54 Fed. Reg. 8973 et seq.) is deemed to take effect as a final rule upon the expiration of such period, and the provisions of paragraph (3) of this subsection are deemed to be incorporated into such rule.

(d) DEFINITIONS.—For purposes of this section:

(1) The term “interim maintenance services” means the provision of methadone in a treatment program under the circumstances described in paragraphs (1) and (2) of subsection (a).

(2) The term “HIV disease” means infection with the etiologic agent for acquired immune deficiency syndrome.

(3) The term “treatment program” means a public or non-profit private program of treatment for dependence on heroin or other morphine-like drugs.

¹ Enacted July 10, 1992.

TITLE XX—ADOLESCENT FAMILY LIFE DEMONSTRATION PROJECTS

FINDINGS AND PURPOSES

SEC. 2001. [300z] (a) The Congress finds that—

(1) in 1978, an estimated one million one hundred thousand teenagers became pregnant, more than five hundred thousand teenagers carried their babies to term, and over one-half of the babies born to such teenagers were born out of wedlock;

(2) adolescents aged seventeen and younger accounted for more than one-half of the out of wedlock births to teenagers;

(3) in a high proportion of cases, the pregnant adolescent is herself the product of an unmarried parenthood during adolescence and is continuing the pattern in her own lifestyle;

(4) it is estimated that approximately 80 per centum of unmarried teenagers who carry their pregnancies to term live with their families before and during their pregnancy and remain with their families after the birth of the child;

(5) pregnancy and childbirth among unmarried adolescents, particularly young adolescents, often results in severe adverse health, social, and economic consequences including: a higher percentage of pregnancy and childbirth complications; a higher incidence of low birth weight babies; a higher infant mortality and morbidity; a greater likelihood that an adolescent marriage will end in divorce; a decreased likelihood of completing schooling; and higher risks of unemployment and welfare dependency; and therefore, education, training, and job research services are important for adolescent parents;

(6)(A) adoption is a positive option for unmarried pregnant adolescents who are unwilling or unable to care for their children since adoption is a means of providing permanent families for such children from available approved couples who are unable or have difficulty in conceiving or carrying children of their own to term; and

(B) at present, only 4 per centum of unmarried pregnant adolescents who carry their babies to term enter into an adoption plan or arrange for their babies to be cared for by relatives or friends;

(7) an unmarried adolescent who becomes pregnant once is likely to experience recurrent pregnancies and childbearing, with increased risks;

(8)(A) the problems of adolescent premarital sexual relations, pregnancy, and parenthood are multiple and complex and are frequently associated with or are a cause of other troublesome situations in the family; and

(B) such problems are best approached through a variety of integrated and essential services provided to adolescents and their families by other family members, religious and charitable organizations, voluntary associations, and other groups in the private sector as well as services provided by publicly sponsored initiatives;

(9) a wide array of educational, health, and supportive services are not available to adolescents with such problems or to their families, or when available frequently are fragmented and thus are of limited effectiveness in discouraging adolescent premarital sexual relations and the consequences of such relations;

(10)(A) prevention of adolescent sexual activity and adolescent pregnancy depends primarily upon developing strong family values and close family ties, and since the family is the basic social unit in which the values and attitudes of adolescents concerning sexuality and pregnancy are formed, programs designed to deal with issues of sexuality and pregnancy will be successful to the extent that such programs encourage and sustain the role of the family in dealing with adolescent sexual activity and adolescent pregnancy;

(B) Federal policy therefore should encourage the development of appropriate health, educational, and social services where such services are now lacking or inadequate, and the better coordination of existing services where they are available; and

(C) services encouraged by the Federal Government should promote the involvement of parents with their adolescent children, and should emphasize the provision of support by other family members, religious and charitable organizations, voluntary associations, and other groups in the private sector in order to help adolescents and their families deal with complex issues of adolescent premarital sexual relations and the consequences of such relations; and

(11)(A) there has been limited research concerning the societal causes and consequences of adolescent pregnancy;

(B) there is limited knowledge concerning which means of intervention are effective in mediating or eliminating adolescent premarital sexual relations and adolescent pregnancy; and

(C) it is necessary to expand and strengthen such knowledge in order to develop an array of approaches to solving the problems of adolescent premarital sexual relations and adolescent pregnancy in both urban and rural settings.

(b) Therefore, the purposes of this title are—

(1) to find effective means, within the context of the family, of reaching adolescents before they become sexually active in order to maximize the guidance and support available to adolescents from parents and other family members, and to promote self discipline and other prudent approaches to the problem of adolescent premarital sexual relations, including adolescent pregnancy;

(2) to promote adoption as an alternative for adolescent parents;

(3) to establish innovative, comprehensive, and integrated approaches to the delivery of care services both for pregnant adolescents, with primary emphasis on unmarried adolescents who are seventeen years of age or under, and for adolescent parents, which shall be based upon an assessment of existing programs and, where appropriate, upon efforts to establish better coordination, integration, and linkages among such existing programs in order to—

(A) enable pregnant adolescents to obtain proper care and assist pregnant adolescents and adolescent parents to become productive independent contributors to family and community life; and

(B) assist families of adolescents to understand and resolve the societal causes which are associated with adolescent pregnancy;

(4) to encourage and support research projects and demonstration projects concerning the societal causes and consequences of adolescent premarital sexual relations, contraceptive use, pregnancy, and child rearing;

(5) to support evaluative research to identify effective services which alleviate, eliminate, or resolve any negative consequences of adolescent premarital sexual relations and adolescent childbearing for the parents, the child, and their families; and

(6) to encourage and provide for the dissemination of results, findings, and information from programs and research projects relating to adolescent premarital sexual relations, pregnancy, and parenthood.

DEFINITIONS

SEC. 2002. [300z-1] (a) For the purposes of this title, the term—

(1) "Secretary" means the Secretary of Health and Human Services;

(2) "eligible person" means—

(A) with regard to the provision of care services, a pregnant adolescent, an adolescent parent, or the family of a pregnant adolescent or an adolescent parent; or

(B) with regard to the provision of prevention services and referral to such other services which may be appropriate, a nonpregnant adolescent;

(3) "eligible grant recipient" means a public or nonprofit private organization or agency which demonstrates, to the satisfaction of the Secretary—

(A) in the case of an organization which will provide care services, the capability of providing all care services in a single setting or the capability of creating a network through which all care services would be provided; or

(B) in the case of an organization which will provide prevention services, the capability of providing such services;

(4) "necessary services" means services which may be provided by grantees which are—

- (A) pregnancy testing and maternity counseling;
 - (B) adoption counseling and referral services which present adoption as an option for pregnant adolescents, including referral to licensed adoption agencies in the community if the eligible grant recipient is not a licensed adoption agency;
 - (C) primary and preventive health services including prenatal and postnatal care;
 - (D) nutrition information and counseling;
 - (E) referral for screening and treatment of venereal disease;
 - (F) referral to appropriate pediatric care;
 - (G) educational services relating to family life and problems associated with adolescent premarital sexual relations, including—
 - (i) information about adoption;
 - (ii) education on the responsibilities of sexuality and parenting;
 - (iii) the development of material to support the role of parents as the provider of sex education; and
 - (iv) assistance to parents, schools, youth agencies, and health providers to educate adolescents and pre-adolescents concerning self-discipline and responsibility in human sexuality;
 - (H) appropriate educational and vocational services;
 - (I) referral to licensed residential care or maternity home services; and
 - (J) mental health services and referral to mental health services and to other appropriate physical health services;
 - (K) child care sufficient to enable the adolescent parent to continue education or to enter into employment;
 - (L) consumer education and homemaking;
 - (M) counseling for the immediate and extended family members of the eligible person;
 - (N) transportation;
 - (O) outreach services to families of adolescents to discourage sexual relations among unemancipated minors;
 - (P) family planning services; and
 - (Q) such other services consistent with the purposes of this title as the Secretary may approve in accordance with regulations promulgated by the Secretary;
- (5) "core services" means those services which shall be provided by a grantee, as determined by the Secretary by regulation;
- (6) "supplemental services" means those services which may be provided by a grantee, as determined by the Secretary by regulation;
- (7) "care services" means necessary services for the provision of care to pregnant adolescents and adolescent parents and includes all core services with respect to the provision of such care prescribed by the Secretary by regulation;
- (8) "prevention services" means necessary services to prevent adolescent sexual relations, including the services de-

scribed in subparagraphs (A), (D), (E), (G), (H), (M), (N), (O), and (Q) of paragraph (4);

(9) "adolescent" means an individual under the age of nineteen; and

(10) "unemancipated minor" means a minor who is subject to the control, authority, and supervision of his or her parents or guardians, as determined under State law.

(b) Until such time as the Secretary promulgates regulations pursuant to the second sentence of this subsection, the Secretary shall use the regulations promulgated under title VI of the Health Services and Centers Amendments of 1978 which were in effect on the date of enactment of this title, to determine which necessary services are core services for purposes of this title. The Secretary may promulgate regulations to determine which necessary services are core services for purposes of this title based upon an evaluation of and information concerning which necessary services are essential to carry out the purposes of this title and taking into account (1) factors such as whether services are to be provided in urban or rural areas, the ethnic groups to be served, and the nature of the populations to be served, and (2) the results of the evaluations required under section 2006(b). The Secretary may from time to time revise such regulations.

AUTHORITY TO MAKE GRANTS FOR DEMONSTRATION PROJECTS

SEC. 2003. [300z-2] (a) The Secretary may make grants to further the purposes of this title to eligible grant recipients which have submitted an application which the Secretary finds meets the requirements of section 2006 for demonstration projects which the Secretary determines will help communities provide appropriate care and prevention services in easily accessible locations. Demonstration projects shall, as appropriate, provide, supplement, or improve the quality of such services. Demonstration projects shall use such methods as will strengthen the capacity of families to deal with the sexual behavior, pregnancy, or parenthood of adolescents and to make use of support systems such as other family members, friends, religious and charitable organizations, and voluntary associations.

(b) Grants under this title for demonstration projects may be for the provision of—

- (1) care services;
- (2) prevention services; or
- (3) a combination of care services and prevention services.

USES OF GRANTS FOR DEMONSTRATION PROJECTS FOR SERVICES

SEC. 2004. [300z-3] (a) Except as provided in subsection (b), funds provided for demonstration projects for services under this title may be used by grantees only to—

(1) provide to eligible persons—

- (A) care services;
- (B) prevention services; or
- (C) care and prevention services (in the case of a grantee who is providing a combination of care and prevention services);

(2) coordinate, integrate, and provide linkages among providers of care, prevention, and other services for eligible persons in furtherance of the purposes of this title;

(3) provide supplemental services where such services are not adequate or not available to eligible persons in the community and which are essential to the care of pregnant adolescents and to the prevention of adolescent premarital sexual relations and adolescent pregnancy;

(4) plan for the administration and coordination of pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents which will further the objectives of this title; and

(5) fulfill assurances required for grant approval by section 2006.

(b)(1) No funds provided for a demonstration project for services under this title may be used for the provision of family planning services (other than counseling and referral services) to adolescents unless appropriate family planning services are not otherwise available in the community.

(2) Any grantee who receives funds for a demonstration project for services under this title and who, after determining under paragraph (1) that appropriate family planning services are not otherwise available in the community, provides family planning services (other than counseling and referral services) to adolescents may only use funds provided under this title for such family planning services if all funds received by such grantee from all other sources to support such family planning services are insufficient to support such family planning services.

(c) Grantees who receive funds for a demonstration project for services under this title shall charge fees for services pursuant to a fee schedule approved by the Secretary as a part of the application described in section 2006 which bases fees charged by the grantee on the income of the eligible person or the parents or legal guardians of the eligible person and takes into account the difficulty adolescents face in obtaining resources to pay for services. A grantee who receives funds for a demonstration project for services under this title may not, in any case, discriminate with regard to the provision of services to any individual because of that individual's inability to provide payment for such services, except that in determining the ability of an unemancipated minor to provide payment for services, the income of the family of an unemancipated minor shall be considered in determining the ability of such minor to make such payments unless the parents or guardians of the unemancipated minor refuse to make such payments.

PRIORITIES, AMOUNTS, AND DURATION OF GRANTS FOR DEMONSTRATION PROJECTS FOR SERVICES

SEC. 2005. [300z-4] (a) In approving applications for grants for demonstration projects for services under this title, the Secretary shall give priority to applicants who—

(1) serve an area where there is a high incidence of adolescent pregnancy;

(2) serve an area with a high proportion of low-income families and where the availability of programs of care for pregnant adolescents and adolescent parents is low;

(3) show evidence—

(A) in the case of an applicant who will provide care services, of having the ability to bring together a wide range of needed core services and, as appropriate, supplemental services in comprehensive single-site projects, or to establish a well-integrated network of such services (appropriate for the target population and geographic area to be served including the special needs of rural areas) for pregnant adolescents or adolescent parents; or

(B) in the case of an applicant who will provide prevention services, of having the ability to provide prevention services for adolescents and their families which are appropriate for the target population and the geographic area to be served, including the special needs of rural areas;

(4) will utilize to the maximum extent feasible existing available programs and facilities such as neighborhood and primary health care centers, maternity homes which provide or can be equipped to provide services to pregnant adolescents, agencies serving families, youth, and children with established programs of service to pregnant adolescents and vulnerable families, licensed adoption agencies, children and youth centers, maternal and infant health centers, regional rural health facilities, school and other educational programs, mental health programs, nutrition programs, recreation programs, and other ongoing pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents;

(5) make use, to the maximum extent feasible, of other Federal, State, and local funds, programs, contributions, and other third-party reimbursements;

(6) can demonstrate a community commitment to the program by making available to the demonstration project non-Federal funds, personnel, and facilities;

(7) have involved the community to be served, including public and private agencies, adolescents, and families, in the planning and implementation of the demonstration project; and

(8) will demonstrate innovative and effective approaches in addressing the problems of adolescent premarital sexual relations, pregnancy, or parenthood, including approaches to provide pregnant adolescents with adequate information about adoption.

(b)(1) The amount of a grant for a demonstration project for services under this title shall be determined by the Secretary, based on factors such as the incidence of adolescent pregnancy in the geographic area to be served, and the adequacy of pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents in such area.

(2) In making grants for demonstration projects for services under this title, the Secretary shall consider the special needs of rural areas and, to the maximum extent practicable, shall distrib-

ute funds taking into consideration the relative number of adolescents in such areas in need of such services.

(c)(1) A grantee may not receive funds for a demonstration project for services under this title for a period in excess of 5 years.

(2)(A) Subject to paragraph (3), a grant for a demonstration project for services under this title may not exceed—

(i) 70 per centum of the costs of the project for the first and second years of the project;

(ii) 60 per centum of such costs for the third year of the project;

(iii) 50 per centum of such costs for the fourth year of the project; and

(iv) 40 per centum of such costs for the fifth year of the project.

(B) Non-Federal contributions required by subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(3) The Secretary may waive the limitation specified in paragraph (2)(A) for any year in accordance with criteria established by regulation.

REQUIREMENTS FOR APPLICATIONS

SEC. 2006. [300z-5] (a) An application for a grant for a demonstration project for services under this title shall be in such form and contain such information as the Secretary may require, and shall include—

(1) an identification of the incidence of adolescent pregnancy and related problems;

(2) a description of the economic conditions and income levels in the geographic area to be served;

(3) a description of existing pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents (including adoption services), and including where, how, by whom, and to which population groups such services are provided, and the extent to which they are coordinated in the geographic area to be served;

(4) a description of the major unmet needs for services for adolescents at risk of initial or recurrent pregnancies and an estimate of the number of adolescents not being served in the area;

(5)(A) in the case of an applicant who will provide care services, a description of how all core services will be provided in the demonstration project using funds under this title or will otherwise be provided by the grantee in the area to be served, the population to which such services will be provided, how such services will be coordinated, integrated, and linked with other related programs and services and the source or sources of funding of such core services in the public and private sectors; or

(B) in the case of an applicant who will provide prevention services, a description of the necessary services to be provided and how the applicant will provide such services;

(6) a description of the manner in which adolescents needing services other than the services provided directly by the applicant will be identified and how access and appropriate referral to such other services (such as medicaid; licensed adoption agencies; maternity home services; public assistance; employment services; child care services for adolescent parents; and other city, county, and State programs related to adolescent pregnancy) will be provided, including a description of a plan to coordinate such other services with the services supported under this title;

(7) a description of the applicant's capacity to continue services as Federal funds decrease and in the absence of Federal assistance;

(8) a description of the results expected from the provision of services, and the procedures to be used for evaluating those results;

(9) a summary of the views of public agencies, providers of services, and the general public in the geographic area to be served, concerning the proposed use of funds provided for a demonstration project for services under this title and a description of procedures used to obtain those views, and, in the case of applicants who propose to coordinate services administered by a State, the written comments of the appropriate State officials responsible for such services;

(10) assurances that the applicant will have an ongoing quality assurance program;

(11) assurances that, where appropriate, the applicant shall have a system for maintaining the confidentiality of patient records in accordance with regulations promulgated by the Secretary;

(12) assurances that the applicant will demonstrate its financial responsibility by the use of such accounting procedures and other requirements as may be prescribed by the Secretary;

(13) assurances that the applicant (A) has or will have a contractual or other arrangement with the agency of the State (in which the applicant provides services) that administers or supervises the administration of a State plan approved under title XIX of the Social Security Act for the payment of all or a part of the applicant's costs in providing health services to persons who are eligible for medical assistance under such a State plan, or (B) has made or will make every reasonable effort to enter into such an arrangement;

(14) assurances that the applicant has made or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to benefits under title V of the Social Security Act, to medical assistance under a State plan approved under title XIX of such Act, or to assistance for medical expenses under any other public assistance program or private health insurance program;

(15) assurances that the applicant has or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing services to per-

sons entitled to services under parts B and E of title IV and title XX of the Social Security Act;

(16)(A) a description of—

(i) the schedule of fees to be used in the provision of services, which shall comply with section 2004(c) and which shall be designed to cover all reasonable direct and indirect costs incurred by the applicant in providing services; and

(ii) a corresponding schedule of discounts to be applied to the payment of such fees, which shall comply with section 2004(c) and which shall be adjusted on the basis of the ability of the eligible person to pay;

(B) assurances that the applicant has made and will continue to make every reasonable effort—

(i) to secure from eligible persons payment for services in accordance with such schedules;

(ii) to collect reimbursement for health or other services provided to persons who are entitled to have payment made on their behalf for such services under any Federal or other government program or private insurance program; and

(iii) to seek such reimbursement on the basis of the full amount of fees for services without application of any discount; and

(C) assurances that the applicant has submitted or will submit to the Secretary such reports as the Secretary may require to determine compliance with this paragraph;

(17) assurances that the applicant will make maximum use of funds available under title X of this Act;

(18) assurances that the acceptance by any individual of family planning services or family planning information (including educational materials) provided through financial assistance under this title shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service furnished by the applicant;

(19) assurances that fees collected by the applicant for services rendered in accordance with this title shall be used by the applicant to further the purposes of this title;

(20) assurances that the applicant, if providing both prevention and care services will not exclude or discriminate against any adolescent who receives prevention services and subsequently requires care services as a pregnant adolescent;

(21) a description of how the applicant will, as appropriate in the provision of services—

(A) involve families of adolescents in a manner which will maximize the role of the family in the solution of problems relating to the parenthood or pregnancy of the adolescent;

(B) involve religious and charitable organizations, voluntary associations, and other groups in the private sector as well as services provided by publicly sponsored initiatives;

(22)(A) assurances that—

(i) except as provided in subparagraph (B) and subject to clause (ii), the applicant will notify the parents or guardians of any unemancipated minor requesting services from the applicant and, except as provided in subparagraph (C), will obtain the permission of such parents or guardians with respect to the provision of such services; and

(ii) in the case of a pregnant unemancipated minor requesting services from the applicant, the applicant will notify the parents or guardians of such minor under clause (i) within a reasonable period of time;

(B) assurances that the applicant will not notify or request the permission of the parents or guardian of any unemancipated minor without the consent of the minor—

(i) who solely is requesting from the applicant pregnancy testing or testing or treatment for venereal disease;

(ii) who is the victim of incest involving a parent; or

(iii) if an adult sibling of the minor or an adult aunt, uncle, or grandparent who is related to the minor by blood certifies to the grantee that notification of the parents or guardians of such minor would result in physical injury to such minor; and

(C) assurances that the applicant will not require, with respect to the provision of services, the permission of the parents or guardians of any pregnant unemancipated minor if such parents or guardians are attempting to compel such minor to have an abortion;

(23) assurances that primary emphasis for services supported under this title shall be given to adolescents seventeen and under who are not able to obtain needed assistance through other means;

(24) assurances that funds received under this title shall supplement and not supplant funds received from any other Federal, State, or local program or any private sources of funds; and

(25) a plan for the conduct of, and assurances that the applicant will conduct, evaluations of the effectiveness of the services supported under this title in accordance with subsection (b).

(b)(1) Each grantee which receives funds for a demonstration project for services under this title shall expend at least 1 per centum but not in excess of 5 per centum of the amounts received under this title for the conduct of evaluations of the services supported under this title. The Secretary may, for a particular grantee upon good cause shown, waive the provisions of the preceding sentence with respect to the amounts to be expended on evaluations, but may not waive the requirement that such evaluations be conducted.

(2) Evaluations required by paragraph (1) shall be conducted by an organization or entity which is independent of the grantee providing services supported under this title. To assist in conducting the evaluations required by paragraph (1), each grantee shall develop a working relationship with a college or university located in the grantee's State which will provide or assist in providing

monitoring and evaluation of services supported under this title unless no college or university in the grantee's State is willing or has the capacity to provide or assist in providing such monitoring and assistance.

(3) The Secretary may provide technical assistance with respect to the conduct of evaluations required under this subsection to any grantee which is unable to develop a working relationship with a college or university in the applicant's State for the reasons described in paragraph (2).

(c) Each grantee which receives funds for a demonstration project for services under this title shall make such reports concerning its use of Federal funds as the Secretary may require. Reports shall include, at such times as are considered appropriate by the Secretary, the results of the evaluations of the services supported under this title.

(d)(1) A grantee shall periodically notify the Secretary of the exact number of instances in which a grantee does not notify the parents or guardians of a pregnant unemancipated minor under subsection (a)(22)(B)(iii).

(2) For purposes of subsection (a)(22)(B)(iii), the term "adult" means an adult as defined by State law.

(e) Each applicant shall provide the Governor of the State in which the applicant is located a copy of each application submitted to the Secretary for a grant for a demonstration project for services under this title. The Governor shall submit to the applicant comments on any such application within the period of sixty days beginning on the day when the Governor receives such copy. The applicant shall include the comments of the Governor with such application.

(f) No application submitted for a grant for a demonstration project for care services under this title may be approved unless the Secretary is satisfied that core services shall be available through the applicant within a reasonable time after such grant is received.

COORDINATION OF FEDERAL AND STATE PROGRAMS

SEC. 2007. [300z-6] (a) The Secretary shall coordinate Federal policies and programs providing services relating to the prevention of adolescent sexual relations and initial and recurrent adolescent pregnancies and providing care services for pregnant adolescents. In achieving such coordination, the Secretary shall—

(1) require grantees who receive funds for demonstration projects for services under this title to report periodically to the Secretary concerning Federal, State, and local policies and programs that interfere with the delivery of and coordination of pregnancy prevention services and other programs of care for pregnant adolescents and adolescent parents;

(2) provide technical assistance to facilitate coordination by State and local recipients of Federal assistance;

(3) review all programs administered by the Department of Health and Human Services which provide prevention services or care services to determine if the policies of such programs are consistent with the policies of this title, consult with other

departments and agencies of the Federal Government who administer programs that provide such services, and encourage such other departments and agencies to make recommendations, as appropriate, for legislation to modify such programs in order to facilitate the use of all Government programs which provide such services as a basis for delivery of more comprehensive prevention services and more comprehensive programs of care for pregnant adolescents and adolescent parents;

(4) give priority in the provision of funds, where appropriate, to applicants using single or coordinated grant applications for multiple programs; and

(5) give priority, where appropriate, to the provision of funds under Federal programs administered by the Secretary (other than the program established by this title) to projects providing comprehensive prevention services and comprehensive programs of care for pregnant adolescents and adolescent parents.

(b) Any recipient of a grant for a demonstration project for services under this title shall coordinate its activities with any other recipient of such a grant which is located in the same locality.

RESEARCH

SEC. 2008. [300z-7] (a)(1) The Secretary may make grants and enter into contracts with public agencies or private organizations or institutions of higher education to support the research and dissemination activities described in paragraphs (4), (5), and (6) of section 2001(b).

(2) The Secretary may make grants or enter into contracts under this section for a period of one year. A grant or contract under this section for a project may be renewed for four additional one-year periods, which need not be consecutive.

(3) A grant or contract for any one-year period under this section may not exceed \$100,000 for the direct costs of conducting research or dissemination¹ activities under this section and may include such additional amounts for the indirect costs of conducting such activities as the Secretary determines appropriate. The Secretary may waive the preceding sentence with respect to a specific project if he determines that—

(A) exceptional circumstances warrant such waiver and that the project will have national impact; or

(B) additional amounts are necessary for the direct costs of conducting limited demonstration projects for the provision of necessary services in order to provide data for research carried out under this title.

(4) The amount of any grant or contract made under this section may remain available for obligation or expenditure after the close of the one-year period for which such grant or contract is made in order to assist the recipient in preparing the report required by subsection (f)(1).

(b)(1) Funds provided for research under this section may be used for descriptive or explanatory surveys, longitudinal studies, or

¹ So in original. Probably should be "dissemination".

limited demonstration projects for services that are for the purpose of increasing knowledge and understanding of the matters described in paragraphs (4) and (5) of section 2001(b).

(2) Funds provided under this section may not be used for the purchase or improvement of land, or the purchase, construction, or permanent improvement (other than minor remodeling) of any building or facility.

(c) The Secretary may not make any grant or enter into any contract to support research or dissemination activities under this section unless—

(1) the Secretary has received an application for such grant or contract which is in such form and which contains such information as the Secretary may by regulation require;

(2) the applicant has demonstrated that the applicant is capable of conducting one or more of the types of research or dissemination activities described in paragraph (4), (5), or (6) of section 2001(b); and

(3) in the case of an application for a research project, the panel established by subsection (e)(2) has determined that the project is of scientific merit.

(d) The Secretary shall, where appropriate, coordinate research and dissemination activities carried out under this section with research and dissemination activities carried out by the National Institutes of Health.

(e)(1) The Secretary shall establish a system for the review of applications for grants and contracts under this section. Such system shall be substantially similar to the system for scientific peer review of the National Institutes of Health and shall meet the requirements of paragraphs (2) and (3).

(2) In establishing the system required by paragraph (1), the Secretary shall establish a panel to review applications under this section. Not more than 25 per centum of the members of the panel shall be physicians. The panel shall meet as often as may be necessary to facilitate the expeditious review of applications under this section, but not less than once each year. The panel shall review each project for which an application is made under this section, evaluate the scientific merit of the project, determine whether the project is of scientific merit, and make recommendations to the Secretary concerning whether the application for the project should be approved.

(3) The Secretary shall make grants under this section from among the projects which the panel established by paragraph (2) has determined to be of scientific merit and may only approve an application for a project if the panel has made such determination with respect to such a project. The Secretary shall make a determination with respect to an application within one month after receiving the determinations and recommendations of such panel with respect to the application.

(f)(1)(A) The recipient of a grant or contract for a research project under this section shall prepare and transmit to the Secretary a report describing the results and conclusions of such research. Except as provided in subparagraph (B), such report shall be transmitted to the Secretary not later than eighteen months after the end of the year for which funds are provided under this

section. The recipient may utilize reprints of articles published or accepted for publication in professional journals to supplement or replace such report if the research contained in such articles was supported under this section during the year for which the report is required.

(B) In the case of any research project for which assistance is provided under this section for two or more consecutive one-year periods, the recipient of such assistance shall prepare and transmit the report required by subparagraph (A) to the Secretary not later than twelve months after the end of each one-year period for which such funding is provided.

(2) Recipients of grants and contracts for dissemination under this section shall submit to the Secretary such reports as the Secretary determines appropriate.

EVALUATION AND ADMINISTRATION

SEC. 2009. [300z-8] (a) Of the funds appropriated under this title, the Secretary shall reserve not less than 1 per centum and not more than 3 per centum for the evaluation of activities carried out under this title. The Secretary shall submit to the appropriate committees of the Congress a summary of each evaluation conducted under this section.

(b) The officer or employee of the Department of Health and Human Services designated by the Secretary to carry out the provisions of this title shall report directly to the Assistant Secretary for Health with respect to the activities of such officer or employee in carrying out such provisions.

AUTHORIZATION OF APPROPRIATIONS

SEC. 2010. [300z-9] (a) For the purpose of carrying out this title, there are authorized to be appropriated \$30,000,000 for the fiscal year ending September 30, 1982, \$30,000,000 for the fiscal year ending September 30, 1983, \$30,000,000 for the fiscal year ending September 30, 1984, and \$30,000,000 for the fiscal year ending September 30, 1985.

(b) At least two-thirds of the amounts appropriated to carry out this title shall be used to make grants for demonstration projects for services.

(c) Not more than one-third of the amounts specified under subsection (b) for use for grants for demonstration projects for services shall be used for grants for demonstration projects for prevention services.

RESTRICTIONS

SEC. 2011. [300z-10] (a) Grants or payments may be made only to programs or projects which do not provide abortions or abortion counseling or referral, or which do not subcontract with or make any payment to any person who provides abortions or abortion counseling or referral, except that any such program or project may provide referral for abortion counseling to a pregnant adolescent if such adolescent and the parents or guardians of such adolescent request such referral; and grants may be made only to projects

or programs which do not advocate, promote, or encourage abortion.

(b) The Secretary shall ascertain whether programs or projects comply with subsection (a) and take appropriate action if programs or projects do not comply with such subsection, including withholding of funds.

TITLE XXI—VACCINES

Subtitle 1—National Vaccine Program

ESTABLISHMENT

SEC. 2101. [300aa-1] The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

PROGRAM RESPONSIBILITIES

SEC. 2102. [300aa-2] (a) The Director of the Program shall have the following responsibilities:

(1) VACCINE RESEARCH.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.

(2) VACCINE DEVELOPMENT.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development to develop the techniques needed to produce safe and effective vaccines.

(3) SAFETY AND EFFICACY TESTING OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

(4) LICENSING OF VACCINE MANUFACTURERS AND VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for the allocation of resources in the implementation of the licensing program under section 353.

(5) PRODUCTION AND PROCUREMENT OF VACCINES.—The Director of the Program shall, through the plan issued under sec-

tion 2103, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

(6) DISTRIBUTION AND USE OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction to the Centers for Disease Control and Prevention and assistance to States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.

(7) EVALUATING THE NEED FOR AND THE EFFECTIVENESS AND ADVERSE EFFECTS OF VACCINES AND IMMUNIZATION ACTIVITIES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Health Care Financing Administration in monitoring the need for and the effectiveness and adverse effects of vaccines and immunization activities.

(8) COORDINATING GOVERNMENTAL AND NON-GOVERNMENTAL ACTIVITIES.—The Director of the Program shall, through the plan issued under section 2103, provide for the exchange of information between Federal agencies involved in the implementation of the Program and non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental activities under the Program.

(9) FUNDING OF FEDERAL AGENCIES.—The Director of the Program shall make available to Federal agencies involved in the implementation of the plan issued under section 2103 funds appropriated under section 2106 to supplement the funds otherwise available to such agencies for activities under the plan.

(b) In carrying out subsection (a) and in preparing the plan under section 2103, the Director shall consult with all Federal agencies involved in research on and development, testing, licensing, production, procurement, distribution, and use of vaccines.

PLAN

SEC. 2103. [300aa-3] The Director of the Program shall prepare and issue a plan for the implementation of the responsibilities of the Director under section 2102. The plan shall establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines, describe an optimal use of resources to carry out such priorities, and

describe how each of the various departments and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with such priorities. The first plan under this section shall be prepared not later than January 1, 1987, and shall be revised not later than January 1 of each succeeding year.

REPORT

SEC. 2104. [300aa-4] The Director shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than January 1, 1988, and annually thereafter on the implementation of the Program and the plan prepared under section 2103.

NATIONAL VACCINE ADVISORY COMMITTEE

SEC. 2105. [300aa-5] (a) There is established the National Vaccine Advisory Committee. The members of the Committee shall be appointed by the Director of the Program, in consultation with the National Academy of Sciences, from among individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations.

(b) The Committee shall—

(1) study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States,

(2) recommend research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines,

(3) advise the Director of the Program in the implementation of sections 2102, 2103, and 2104, and

(4) identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 2102, 2103, and 2104.

AUTHORIZATIONS

SEC. 2106. [300aa-6] (a) To carry out this subtitle other than section 2102(9) there are authorized to be appropriated \$4,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.

(b) To carry out section 2102(9) there are authorized to be appropriated \$30,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.

Subtitle 2—National Vaccine Injury Compensation Program

PART A—PROGRAM REQUIREMENTS

ESTABLISHMENT OF PROGRAM

SEC. 2110. [300aa-10] (a) PROGRAM ESTABLISHED.—There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

(b) ATTORNEY'S OBLIGATION.—It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program for such injury or death.

(c) PUBLICITY.—The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

PETITIONS FOR COMPENSATION

SEC. 2111. [300aa-11] (a) GENERAL RULE.—

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) with the United States Claims Court. The clerk of the United States Claims Court shall immediately forward the filed petition to the chief special master for assignment to a special master under section 2112(d)(1).

(2)(A) No person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part, and no such court may award damages in an amount greater than \$1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 2116, for compensation under the Program for such injury or death and—

(i)(I) the United States Claims Court has issued a judgment under section 2112 on such petition, and

(II) such person elects under section 2121(a) to file such an action, or

(ii) such person elects to withdraw such petition under section 2121(b) or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 2116, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part.¹

(4) If in a civil action brought against a vaccine administrator or manufacturer before the effective date of this part¹ damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) for such injury or death.

(5)(A) A plaintiff who on the effective date of this part¹ has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after the effective date of this part¹ or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) for such injury or death.

(6) If a person brings a civil action after November 15, 1988 for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under subsection (b) for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) for such injury or death.

(8) If on the effective date of this part there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition under subsection (b) for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) PETITIONERS.—

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine In-

¹ Effective October 1, 1988.

jury Table may, if the person meets the requirements of subsection (c)(1), file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before the effective date of this part if compensation has been paid under this subtitle for 3500 petitions for such injuries or deaths.

(2) Only one petition may be filed with respect to each administration of a vaccine.

(c) PETITION CONTENT.—A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the

onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine and incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than \$1,000, or (ii) died from the administration of the vaccine, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) **ADDITIONAL INFORMATION.**—A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) **SCHEDULE.**—The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

JURISDICTION

SEC. 2112. [300aa-12] (a) **GENERAL RULE.**—The United States Claims Court and the United States Claims Court special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 2111 is entitled to compensation under the Program and the amount of such compensation. The United States Claims Court may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) **PARTIES.**—

(1) In all proceedings brought by the filing of a petition under section 2111(b), the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28, United States Code.

(2) Within 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the Federal Register. The special

master designated with respect to such petition under subsection (c) shall afford all interested persons an opportunity to submit relevant, written information—

(A) relating to the existence of the evidence described in section 2113(a)(1)(B), or

(B) relating to any allegation in a petition with respect to the matters described in section 2111(c)(1)(C)(ii).

(c) UNITED STATES CLAIMS COURT SPECIAL MASTERS.—

(1) There is established within the United States Claims Court an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Claims Court shall appoint the special masters, 1 of whom, by designation of the judges of the United States Claims Court, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Claims Court for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Claims Court determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters upon the date of the enactment of this subsection shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on the date of the enactment of this subsection shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States Claims Court, upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, title 5, United States Code. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, title 5, United States Code.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall

be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrates shall be applied to the special masters.

(D) Coordinating with the United States Claims Court the use of services, equipment, personnel, information, and facilities of the United States Claims Court without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Claims Court on the number of petitions filed under section 2111 and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) SPECIAL MASTERS.—

(1) Following the receipt and filing of a petition under section 2111, the clerk of the United States Claims Court shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Claims Court and, taking into account such recommended rules, the Claims Court shall promulgate rules pursuant to section 2071 of title 28, United States Code. Such rules shall—

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Claims Court.

(3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall—

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Claims Court in accordance with subsection (e).

(B) In conducting a proceeding on a petition a special master—

(i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) shall afford all interested persons an opportunity to submit relevant written information—

(I) relating to the existence of the evidence described in section 2113(a)(1)(B), or

(II) relating to any allegation in a petition with respect to the matters described in section 2111(c)(1)(C)(ii), and

(v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before the effective date of this part, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information—

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) ACTION BY THE UNITED STATES CLAIMS COURT.—

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Claims Court a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Claims Court no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Claims Court shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Claims Court takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Claims Court shall immediately enter judgment in accordance with the special master's decision.

(f) APPEALS.—The findings of fact and conclusions of law of the United States Claims Court on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the date of entry of the United States Claims Court's judgment with such court of appeals.

(g)¹ NOTICE.—If—

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)), or

(2) the United States Claims Court fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or

¹ Subsection (i)(2) of section 201 of Public Law 102-168 (105 Stat. 1104), which was enacted on November 26, 1991, provided that the amendments made by subsections (d) and (f) of such section "shall take effect as if the amendments had been in effect on and after October 1, 1988". Such subsections (d) and (f) related to actions by petitioners, and to annuities, respectively, and involved amendments to sections 2112(g), 2115(f)(4), 2116(c), and 2121(b).

(d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)) after the date on which the petition was filed, the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 2121(b) or the petitioner may choose under section 2121(b) to have the petition remain before the special master or court, as the case may be.

DETERMINATION OF ELIGIBILITY AND COMPENSATION

SEC. 2113. [300aa-13] (a) GENERAL RULE.—

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 2111(c)(1), and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term “factors unrelated to the administration of the vaccine”—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) MATTERS TO BE CONSIDERED.—

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary,

the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

(c) RECORD DEFINED.—For purposes of this section, the term “record” means the record established by the special masters of the United States Claims Court in a proceeding on a petition filed under section 2111.

VACCINE INJURY TABLE

SEC. 2114. [300aa-14] (a) INITIAL TABLE.—The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

I.	DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
	Illness, disability, injury, or condition covered:	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	3 days
	C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
	D. Residual seizure disorder in accordance with subsection (b)(2)	3 days
	E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
II.	Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	

A. Anaphylaxis or anaphylactic shock	24 hours
B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
C. Residual seizure disorder in accordance with subsection (b)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
III. Polio Vaccines (other than Inactivated Polio Vaccine).	
A. Paralytic polio	
—in a non-immunodeficient recipient	30 days
—in an immunodeficient recipient	6 months
—in a vaccine-associated community case	Not applicable
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
IV. Inactivated Polio Vaccine.	
A. Anaphylaxis or anaphylactic shock	24 hours
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

(b) **QUALIFICATIONS AND AIDS TO INTERPRETATION.**—The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a):

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent inconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 2111 for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

(c) ADMINISTRATIVE REVISION OF THE TABLE.—

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rule-making proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) **ROLE OF COMMISSION.**—Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

(e)¹ **ADDITIONAL VACCINES.**—

(1) **VACCINES RECOMMENDED BEFORE AUGUST 1, 1993.**—By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) **VACCINES RECOMMENDED AFTER AUGUST 1, 1993.**—When after August 1, 1993, the Centers for Disease Control and Pre-

¹ Section 13632(a)(3) of Public Law 103-66 (107 Stat. 646) provides as follows:

“(3) **EFFECTIVE DATE.**—A revision by the Secretary under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa-14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa-14(a)).”.

vention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which were recommended for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

COMPENSATION

SEC. 2115. [300aa-15] (a) GENERAL RULE.—Compensation awarded under the Program to a petitioner under section 2111 for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part¹ shall include the following:

(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—

(i) result from the vaccine-related injury for which the petitioner seeks compensation,

(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(B) Subject to section 2116(a)(2), actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of a vaccine-related death, an award of \$250,000 for the estate of the deceased.

¹ Effective October 1, 1988.

(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed \$250,000.

(b) VACCINES ADMINISTERED BEFORE THE EFFECTIVE DATE.—Compensation awarded under the Program to a petitioner under section 2111 for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part¹ may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of \$30,000, for—

(1) lost earnings (as provided in paragraph (3) of subsection (a)),

(2) pain and suffering (as provided in paragraph (4) of subsection (a)), and

(3) reasonable attorneys' fees and costs (as provided in subsection (e)).

(c) RESIDENTIAL AND CUSTODIAL CARE AND SERVICE.—The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

(d) TYPES OF COMPENSATION PROHIBITED.—Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

(e) ATTORNEYS' FEES.—

(1) In awarding compensation on a petition filed under section 2111 the special master or court shall also award as part of such compensation an amount to cover—

(A) reasonable attorneys' fees, and

¹ Effective October 1, 1988.

(B) other costs, incurred in any proceeding on such petition. If the judgment of a special master or court on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) If the petitioner, before the effective date of this part,¹ filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and petitioned under section 2111(a)(5) to have such action dismissed and to file a petition for compensation under the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before the effective date of this part¹ in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

(3) No attorney may charge any fee for services in connection with a petition filed under section 2111 which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(f) PAYMENT OF COMPENSATION.—

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 2121(a) to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the United States Claims Court under section 2112 awarding the compensation. Such compensation may not be paid after an election under section 2121(a) to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation under the Program and the costs of carrying out the Program shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985.

(4)(A)¹ Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Vaccine Injury Compensation Trust Fund established under section 9510 of the Internal Revenue Code of 1986 in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in

¹ See footnote 1 on page 766.

a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part¹ the compensation shall be determined on the basis of the net present value of the elements of compensation and paid in 4 equal annual installments of which all or a portion of the proceeds² may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 2121(a) shall not apply to a civil action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Vaccine Injury Compensation Trust Fund established under section 9510 of the Internal Revenue Code of 1986, or to the appropriations account from which the funds were derived to purchase the annuity, whichever is appropriate.

(g) PROGRAM NOT PRIMARILY LIABLE.—Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (other than under title XIX of the Social Security Act), or (2) by an entity which provides health services on a prepaid basis.

(h) LIABILITY OF HEALTH INSURANCE CARRIERS, PREPAID HEALTH PLANS, AND BENEFIT PROVIDERS.—No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

(1) no State, and

(2) no entity which provides health services on a prepaid basis or provides health benefits, may make the provision of health services or health benefits secondary to the payment of compensation under the Program, except

¹Effective October 1, 1988.

²Section 201(e)(1)(B) of Public Law 102-168 (105 Stat. 1103) provided that this subparagraph is amended by striking out "paid in 4 equal installments of which all or portion of the proceeds" and inserting in lieu thereof "shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion". The amendment cannot be executed because the term to be struck does not appear in the law. (Compare "equal installments" with "equal annual installments" and "or portion" with "or a portion".)

that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act.

(i) SOURCE OF COMPENSATION.—

(1) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part¹ shall be made by the Secretary from appropriations under subsection (j).

(2) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine on or after the effective date of this part¹ shall be made from the Vaccine Injury Compensation Trust Fund established under section 9510 of the Internal Revenue Code of 1986.

(j) AUTHORIZATION.—For the payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part¹ there are authorized to be appropriated to the Department of Health and Human Services \$80,000,000 for fiscal year 1989, \$80,000,000 for fiscal year 1990, \$80,000,000 for fiscal year 1991, \$80,000,000 for fiscal year 1992, \$110,000,000 for fiscal year 1993, and \$110,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B). Amounts appropriated under this subsection shall remain available until expended.

LIMITATIONS OF ACTIONS

SEC. 2116. [300aa-16] (a) GENERAL RULE.—In the case of—

(1) a vaccine set forth in the Vaccine Injury Table which is administered before the effective date of this part,¹ if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 28 months after the effective date of this part¹ and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine,

(2) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this part,¹ if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

(3) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this part,¹ if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48

¹ Effective October 1, 1988.

months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

(b) EFFECT OF REVISED TABLE.—If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 2111(b)(2), file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if—

(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

(c)¹ STATE LIMITATIONS OF ACTIONS.—If a petition is filed under section 2111 for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date (1) an election is made under section 2121(a) to file the civil action or (2) an election is made under section 2121(b) to withdraw the petition.

SUBROGATION

SEC. 2117. [300aa-17] (a) GENERAL RULE.—Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrogated to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

(b) DISPOSITION OF AMOUNTS RECOVERED.—Amounts recovered under subsection (a) shall be collected on behalf of, and deposited in, the Vaccine Injury Compensation Trust Fund established under section 9510 of the Internal Revenue Code of 1986.

ADVISORY COMMISSION ON CHILDHOOD VACCINES

SEC. 2119. [300aa-19] (a) ESTABLISHMENT.—There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

(1) Nine members appointed by the Secretary as follows:

(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

¹ See footnote 1 on page 764.

(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of the effective date of this part.¹ The members of the Commission shall select a Chair from among the members.

(b) TERM OF OFFICE.—Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

(c) MEETINGS.—The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the Commission present at the meeting.

(d) COMPENSATION.—Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the Commission who are not officers or employees of the Federal Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for employees serving intermittently.

(e) STAFF.—The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

(f) FUNCTIONS.—The Commission shall—

(1) advise the Secretary on the implementation of the Program,

(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

¹ Effective October 1, 1988.

(3) advise the Secretary in implementing the Secretary's responsibilities under section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b), and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this subtitle.

PART B—ADDITIONAL REMEDIES

AUTHORITY TO BRING ACTIONS

SEC. 2121. [300aa-21] (a) ELECTION.—After judgment has been entered by the United States Claims Court or, if an appeal is taken under section 2112(f), after the appellate court's mandate is issued, the petitioner who filed the petition under section 2111 shall file with the clerk of the United States Claims Court—

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the court's final judgment with respect to which the election is to be made. If a person required to file an election with the court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered. For limitations on the bringing of civil actions for vaccine-related injuries or deaths associated with the administration of a vaccine after the effective date of this part¹, see section 2111(a)(2).

(b)² CONTINUANCE OR WITHDRAWAL OF PETITION.³—A petitioner under a petition filed under section 2111 may submit to the

¹Effective October 1, 1988.

²See footnote 1 on page 764.

³The amendment described in section 201(d)(3)(C) of Public Law 102-168 (105 Stat. 1103) has been executed according to the probable intent of the Congress. After redesignating former subparagraphs (A) and (B) as paragraphs (1) and (2), the amendatory instructions of the section provided that section 2121(b) is amended "by running, the text of paragraph (1) into the sub-

Continued

United States Claims Court a notice in writing choosing to continue or to withdraw the petition if—

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 2112(d)(3)(A)(ii) (excluding (i) any period of suspension under section 2112(d)(3)(C) or 2112(d)(3)(D), and (ii) any days the petition is before a special master as a result of a remand under section 2112(e)(2)(C)), or

(2) the court fails to enter a judgment under section 2112 on the petition within 420 days (excluding (i) any period of suspension under section 2112(d)(3)(C) or 2112(d)(3)(D), and (ii) any days the petition is before a special master as a result of a remand under section 2112(e)(2)(C)) after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 2112(g).

(c) LIMITATIONS OF ACTIONS.—A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 2111 shall, except as provided in section 2116(c), be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

STANDARDS OF RESPONSIBILITY

SEC. 2122. [300aa-22] (a) GENERAL RULE.—Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) UNAVOIDABLE ADVERSE SIDE EFFECTS; WARNINGS.—

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part¹ if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 2123(d)(2), or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

section heading and making the margin of the text full measure". The instructions were applied to portions of the matter preceding paragraph (1) (as redesignated, rather than to the text of paragraph (1). (That is, the instructions were applied to the former paragraph (1).)

¹ Effective October 1, 1988.

(c) **DIRECT WARNINGS.**—No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part¹ solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) **CONSTRUCTION.**—The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) **PREEMPTION.**—No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle.

TRIAL

SEC. 2123. [300aa-23] (a) GENERAL RULE.—A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part¹ which is not barred by section 2111(a)(2) shall be tried in three stages.

(b) **LIABILITY.**—The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 2122.

(c) **GENERAL DAMAGES.**—The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 2122 shall be required to pay.

(d) **PUNITIVE DAMAGES.**—

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 2122 shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 351,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

¹ Effective October 1, 1988.

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) EVIDENCE.—In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Claims Court or a special master in a proceeding on a petition filed under section 2111 and the final judgment of the United States Claims Court and subsequent appellate review on such a petition shall not be admissible.

PART C—ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN THE UNITED STATES

RECORDING AND REPORTING OF INFORMATION

SEC. 2125. [300aa-25] (a) GENERAL RULE.—Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

- (1) the date of administration of the vaccine,
- (2) the vaccine manufacturer and lot number of the vaccine,
- (3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and
- (4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(b) REPORTING.—

(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 2114(b) which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after the effective date of this part.¹ The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

¹ Effective December 22, 1987.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of the effective date of this part.¹

(c) RELEASE OF INFORMATION.—

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, United States Code, or otherwise, to any person except—

(A) the person who received the vaccine, or

(B) the legal representative of such person.

(2) For purposes of paragraph (1), the term “information which may identify an individual” shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person’s legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

VACCINE INFORMATION

SEC. 2126. [300aa–26] (a) GENERAL RULE.—Not later than 1 year after the effective date of this part,¹ the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

(b) DEVELOPMENT AND REVISION OF MATERIALS.—Such materials shall be developed or revised—

(1) after notice to the public and 60 days of comment thereon, and

(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

(c) INFORMATION REQUIREMENTS.—The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include—

(1) a concise description of the benefits of the vaccine,

(2) a concise description of the risks associated with the vaccine,

(3) a statement of the availability of the National Vaccine Injury Compensation Program, and

¹ Effective December 22, 1987.

(4) such other relevant information as may be determined by the Secretary.

(d) HEALTH CARE PROVIDER DUTIES.—On and after a date determined by the Secretary which is—

(1) after the Secretary develops the information materials required by subsection (a), and

(2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

MANDATE FOR SAFER CHILDHOOD VACCINES

SEC. 2127. [300aa-27] (a) GENERAL RULE.—In the administration of this subtitle and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on the effective date of this part¹ and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) TASK FORCE.—

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) REPORT.—Within 2 years after the effective date of this part,¹ and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

¹Effective December 22, 1987.

MANUFACTURER RECORDKEEPING AND REPORTING

SEC. 2128. [300aa-28] (a) GENERAL RULE.—Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to each batch, lot, or other quantity manufactured or licensed after the effective date of this part—¹

(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous batches, lots, or other quantities (and, if so, the identity of the previous batches, lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test,

(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

(b) SANCTION.—Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall—

(1) be subject to a civil penalty of up to \$100,000 per occurrence, or

(2) be fined \$50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or concealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

PART D—GENERAL PROVISIONS

CITIZEN'S ACTIONS

SEC. 2131. [300aa-31] (a) GENERAL RULE.—Except as provided in subsection (b), any person may commence in a district

¹ Effective December 22, 1987.

court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this subtitle.

(b) NOTICE.—No action may be commenced under subsection (a) before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

(c) COSTS OF LITIGATION.—The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any plaintiff who substantially prevails on one or more significant issues in the action.

JUDICIAL REVIEW

SEC. 2132. [300aa-32] A petition for review of a regulation under this subtitle may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

DEFINITIONS

SEC. 2133. [300aa-33] For purposes of this subtitle:

(1) The term "health care provider" means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

(2) The term "legal representative" means a parent or an individual who qualifies as a legal guardian under State law.

(3) The term "manufacturer" means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 2128, such term shall include the manufacturer of any other vaccine covered by that section. The term "manufacture" means to manufacture, import, process, or distribute a vaccine.

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

(5) The term "vaccine-related injury or death" means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

(6)(A) The term "Advisory Commission on Childhood Vaccines" means the Commission established under section 2119.

(B) The term "Vaccine Injury Table" means the table set out in section 2114.

TERMINATION OF PROGRAM

SEC. 2134. [300aa-34] (a) **REVIEWS.**—The Secretary shall review the number of awards of compensation made under the program to petitioners under section 2111 for vaccine-related injuries and deaths associated with the administration of vaccines on or after the effective date of this part¹ as follows:

(1) The Secretary shall review the number of such awards made in the 12-month period beginning on the effective date of this part.¹

(2) At the end of each 3-month period beginning after the expiration of the 12-month period referred to in paragraph (1) the Secretary shall review the number of such awards made in the 3-month period.

(b) **REPORT.**—

(1) If in conducting a review under subsection (a) the Secretary determines that at the end of the period reviewed the total number of awards made by the end of that period and accepted under section 2121(a) exceeds the number of awards listed next to the period reviewed in the table in paragraph (2)—

(A) the Secretary shall notify the Congress of such determination, and

(B) beginning 180 days after the receipt by Congress of a notification under paragraph (1), no petition for a vaccine-related injury or death associated with the administration of a vaccine on or after the effective date of this part¹ may be filed under section 2111.

Section 2111(a) and part B shall not apply to civil actions for damages for a vaccine-related injury or death for which a petition may not be filed because of subparagraph (B).

(2) The table referred to in paragraph (1) is as follows:

Period reviewed:	Total number of awards by the end of the period reviewed
12 months after the effective date of part	150
13th through the 15th month after such date	188
16th through the 18th month after such date	225
19th through the 21st month after such date	263
22nd through the 24th month after such date	300
25th through the 27th month after such date	338
28th through the 30th month after such date	375
31st through the 33rd month after such date	413
34th through the 36th month after such date	450
37th through the 39th month after such date	488
40th through the 42nd month after such date	525
43rd through the 45th month after such date	563
46th through the 48th month after such date	600.

¹ Effective December 22, 1987.

TITLE XXII—REQUIREMENTS FOR CERTAIN GROUP HEALTH PLANS FOR CERTAIN STATE AND LOCAL EMPLOYEES

SEC. 2201. [300bb-1] STATE AND LOCAL GOVERNMENTAL GROUP HEALTH PLANS MUST PROVIDE CONTINUATION COVERAGE TO CERTAIN INDIVIDUALS.

(a) IN GENERAL.—In accordance with regulations which the Secretary shall prescribe, each group health plan that is maintained by any State that receives funds under this Act, by any political subdivision of such a State, or by any agency or instrumentality of such a State or political subdivision, shall provide, in accordance with this title, that each qualified beneficiary who would lose coverage under the plan as a result of a qualifying event is entitled, under the plan, to elect, within the election period, continuation coverage under the plan.

(b) EXCEPTION FOR CERTAIN PLANS.—Subsection (a) shall not apply to—

(1) any group health plan for any calendar year if all employers maintaining such plan normally employed fewer than 20 employees on a typical business day during the preceding calendar year, or

(2) any group health plan maintained for employees by the government of the District of Columbia or any territory or possession of the United States or any agency or instrumentality.

SEC. 2202. [300bb-2] CONTINUATION COVERAGE.

For purposes of section 2201, the term “continuation coverage” means coverage under the plan which meets the following requirements:

(1) TYPE OF BENEFIT COVERAGE.—The coverage must consist of coverage which, as of the time the coverage is being provided, is identical to the coverage provided under the plan to similarly situated beneficiaries under the plan with respect to whom a qualifying event has not occurred. If coverage is modified under the plan for any group of similarly situated beneficiaries, such coverage shall also be modified in the same manner for all individuals who are qualified beneficiaries under the plan pursuant to this part¹ in connection with such group.

(2) PERIOD OF COVERAGE.—The coverage must extend for at least the period beginning on the date of the qualifying event and ending not earlier than the earliest of the following:

(A) MAXIMUM REQUIRED PERIOD.—

(i) GENERAL RULE FOR TERMINATIONS AND REDUCED HOURS.—In the case of a qualifying event described in section 2203(2), except as provided in clause

¹ So in original. This title is not divided into parts.

(ii), the date which is 18 months after the date of the qualifying event.

(ii) SPECIAL RULE FOR MULTIPLE QUALIFYING EVENTS.—If a qualifying event occurs during the 18 months after the date of a qualifying event described in section 2203(2), the date which is 36 months after the date of the qualifying event described in section 2203(2).

(iii) GENERAL RULE FOR OTHER QUALIFYING EVENTS.—In the case of a qualifying event not described in section 2203(2), the date which is 36 months after the date of the qualifying event.

In¹ the case of an individual who is determined, under title II or XVI of the Social Security Act, to have been disabled at the time of a qualifying event described in section 2203(2), any reference in clause (i) or (ii) to 18 months with respect to such event is deemed a reference to 29 months, but only if the qualified beneficiary has provided notice of such determination under section 2206(3) before the end of such 18 months.

(iv) QUALIFYING EVENT INVOLVING MEDICARE ENTITLEMENT.—In the case of an event described in section 2203(4) (without regard to whether such event is a qualifying event), the period of coverage for qualified beneficiaries other than the covered employee for such event or any subsequent qualifying event shall not terminate before the close of the 36-month period beginning on the date the covered employee becomes entitled to benefits under title XVIII of the Social Security Act.

(B) END OF PLAN.—The date on which the employer ceases to provide any group health plan to any employee.

(C) FAILURE TO PAY PREMIUM.—The date on which coverage ceases under the plan by reason of a failure to make timely payment of any premium required under the plan with respect to the qualified beneficiary. The payment of any premium (other than any payment referred to in the last sentence of paragraph (3)) shall be considered to be timely if made within 30 days after the date due or within such longer period as applies to or under the plan.

(D) GROUP HEALTH PLAN COVERAGE OR MEDICARE ENTITLEMENT.—The date on which the qualified beneficiary first becomes, after the date of the election—

(i) covered under any other group health plan (as an employee or otherwise) which does not contain any exclusion or limitation with respect to any preexisting condition of such beneficiary, or

(ii) entitled to benefits under title XVIII of the Social Security Act.

¹ Placement is so in original. Section 6702(a) of Public Law 101-239 amended section 2202(2) in subparagraph (A) "by adding after and below clause (iii)" the above language, which clause (iii) was at that time the last clause of subparagraph (A). Section 6801(b)(1) of Public Law 101-239 then amended the same subparagraph "by adding at the end" a clause (iv).

(E) **TERMINATION OF EXTENDED COVERAGE FOR DISABILITY.**—In the case of a qualified beneficiary who is disabled at the time of a qualifying event described in section 2203(2), the month that begins more than 30 days after the date of the final determination under title II or XVI of the Social Security Act that the qualified beneficiary is no longer disabled.

(3) **PREMIUM REQUIREMENTS.**—The plan may require payment of a premium for any period of continuation coverage, except that such premium—

(A) shall not exceed 102 percent of the applicable premium for such period, and

(B) may, at the election of the payor, be made in monthly installments.

In no event may the plan require the payment of any premium before the day which is 45 days after the day on which the qualified beneficiary made the initial election for continuation coverage. In the case of an individual described in the last sentence of paragraph (2)(A)¹, any reference in subparagraph (A) of this paragraph to “102 percent” is deemed a reference to “150 percent” for any month after the 18th month of continuation coverage described in clause (i) or (ii) of paragraph (2)(A).

(4) **NO REQUIREMENT OF INSURABILITY.**—The coverage may not be conditioned upon, or discriminate on the basis of lack of, evidence of insurability.

(5) **CONVERSION OPTION.**—In the case of a qualified beneficiary whose period of continuation coverage expires under paragraph (2)(A), the plan must, during the 180-day period ending on such expiration date, provide to the qualified beneficiary the option of enrollment under a conversion health plan otherwise generally available under the plan.

SEC. 2203. [300bb-3] QUALIFYING EVENT.

For purposes of this title, the term “qualifying event” means, with respect to any covered employee, any of the following events which, but for the continuation coverage required under this title, would result in the loss of coverage of a qualified beneficiary:

(1) The death of the covered employee.

(2) The termination (other than by reason of such employee's gross misconduct), or reduction of hours, of the covered employee's employment.

(3) The divorce or legal separation of the covered employee from the employee's spouse.

(4) The covered employee becoming entitled to benefits under title XVIII of the Social Security Act.

(5) A dependent child ceasing to be a dependent child under the generally applicable requirements of the plan.

SEC. 2204. [300bb-4] APPLICABLE PREMIUM.

For purposes of this title—

(1) **IN GENERAL.**—The term “applicable premium” means, with respect to any period of continuation coverage of qualified

¹So in original. Probably is meant to be a reference to an individual described in the matter after and below clause (iii) of paragraph (2)(A). See footnote 1 on page 789.

beneficiaries, the cost to the plan for such period of the coverage for similarly situated beneficiaries with respect to whom a qualifying event has not occurred (without regard to whether such cost is paid by the employer or employee).

(2) SPECIAL RULE FOR SELF-INSURED PLANS.—To the extent that a plan is a self-insured plan—

(A) IN GENERAL.—Except as provided in subparagraph (B), the applicable premium for any period of continuation coverage of qualified beneficiaries shall be equal to a reasonable estimate of the cost of providing coverage for such period for similarly situated beneficiaries which—

(i) is determined on an actuarial basis, and

(ii) takes into account such factors as the Secretary may prescribe in regulations.

(B) DETERMINATION ON BASIS OF PAST COST.—If a plan administrator elects to have this subparagraph apply, the applicable premium for any period of continuation coverage of qualified beneficiaries shall be equal to—

(i) the cost to the plan for similarly situated beneficiaries for the same period occurring during the preceding determination period under paragraph (3), adjusted by

(ii) the percentage increase or decrease in the implicit price deflator of the gross national product (calculated by the Department of Commerce and published in the Survey of Current Business) for the 12-month period ending on the last day of the sixth month of such preceding determination period.

(C) SUBPARAGRAPH (B) NOT TO APPLY WHERE SIGNIFICANT CHANGE.—A plan administrator may not elect to have subparagraph (B) apply in any case in which there is any significant difference, between the determination period and the preceding determination period, in coverage under, or in employees covered by, the plan. The determination under the preceding sentence for any determination period shall be made at the same time as the determination under paragraph (3).

(3) DETERMINATION PERIOD.—The determination of any applicable premium shall be made for a period of 12 months and shall be made before the beginning of such period.

SEC. 2205. [300bb-5] ELECTION.

For purposes of this title—

(1) ELECTION PERIOD.—The term “election period” means the period which—

(A) begins not later than the date on which coverage terminates under the plan by reason of a qualifying event,

(B) is of at least 60 days' duration, and

(C) ends not earlier than 60 days after the later of—

(i) the date described in subparagraph (A), or

(ii) in the case of any qualified beneficiary who receives notice under section 2206(4), the date of such notice.

(2) EFFECT OF ELECTION ON OTHER BENEFICIARIES.—Except as otherwise specified in an election, any election of continuation coverage by a qualified beneficiary described in subparagraph (A)(i) or (B) of section 2208(3) shall be deemed to include an election of continuation coverage on behalf of any other qualified beneficiary who would lose coverage under the plan by reason of the qualifying event. If there is a choice among types of coverage under the plan, each qualified beneficiary is entitled to make a separate selection among such types of coverage.

SEC. 2206. [300bb-6] NOTICE REQUIREMENTS.

In accordance with regulations prescribed by the Secretary—

(1) the group health plan shall provide, at the time of commencement of coverage under the plan, written notice to each covered employee and spouse of the employee (if any) of the rights provided under this subsection,¹

(2) the employer of an employee under a plan must notify the plan administrator of a qualifying event described in paragraph (1), (2), or (4) of section 2203 within 30 days of the date of the qualifying event,

(3) each covered employee or qualified beneficiary is responsible for notifying the plan administrator of the occurrence of any qualifying event described in paragraph (3) or (5) of section 2203 within 60 days after the date of the qualifying event and each qualified beneficiary who is determined, under title II or XVI of the Social Security Act, to have been disabled at the time of a qualifying event described in section 2203(2) is responsible for notifying the plan administrator of such determination within 60 days after the date of the determination and for notifying the plan administrator within 30 days after the date of any final determination under such title or titles that the qualified beneficiary is no longer disabled, and

(4) the plan administrator shall notify—

(A) in the case of a qualifying event described in paragraph (1), (2), or (4) of section 2203, any qualified beneficiary with respect to such event, and

(B) in the case of a qualifying event described in paragraph (3) or (5) of section 2203 where the covered employee notifies the plan administrator under paragraph (3), any qualified beneficiary with respect to such event,

of such beneficiary's rights under this subsection.¹

For purposes of paragraph (4), any notification shall be made within 14 days of the date on which the plan administrator is notified under paragraph (2) or (3), whichever is applicable, and any such notification to an individual who is a qualified beneficiary as the spouse of the covered employee shall be treated as notification to all other qualified beneficiaries residing with such spouse at the time such notification is made.

¹ So in original. Probably should be "this title".

SEC. 2207.¹ [300bb-7] ENFORCEMENT.

Any individual who is aggrieved by the failure of a State, political subdivision, or agency or instrumentality thereof, to comply with the requirements of this title may bring an action for appropriate equitable relief.

SEC. 2208. [300bb-8] DEFINITIONS.

For purposes of this title—

(1) **GROUP HEALTH PLAN.**—The term “group health plan” has the meaning given such term in section 162(i)(2) of the Internal Revenue Code of 1986.

(2) **COVERED EMPLOYEE.**—The term “covered employee” means an individual who is (or was) provided coverage under a group health plan by virtue of the performance of services by the individual for 1 or more persons maintaining the plan (including as an employee defined in section 401(c)(1) of the Internal Revenue Code of 1986).

(3) **QUALIFIED BENEFICIARY.**—

(A) **IN GENERAL.**—The term “qualified beneficiary” means, with respect to a covered employee under a group health plan, any other individual who, on the day before the qualifying event for that employee, is a beneficiary under the plan—

(i) as the spouse of the covered employee, or

(ii) as the dependent child of the employee.

(B) **SPECIAL RULE FOR TERMINATIONS AND REDUCED EMPLOYMENT.**—In the case of a qualifying event described in section 2203(2), the term “qualified beneficiary” includes the covered employee.

(4) **PLAN ADMINISTRATOR.**—The term “plan administrator” has the meaning given the term “administrator” by section 3(16)(A) of the Employee Retirement Income Security Act of 1974.

¹Section 13631(d) of Public Law 103-66 (107 Stat. 643) provides as follows:

“(d) **CONTINUED COVERAGE OF COSTS OF A PEDIATRIC VACCINE UNDER CERTAIN GROUP HEALTH PLANS.**—

“(1) **REQUIREMENT.**—The requirement of this paragraph, with respect to a group health plan for plan years beginning after the date of the enactment of this Act, is that the group health plan not reduce its coverage of the costs of pediatric vaccines (as defined under section 1928(h)(6) of the Social Security Act) below the coverage it provided as of May 1, 1993.

“(2) **ENFORCEMENT.**—For purposes of section 2207 of the Public Health Service Act, the requirement of paragraph (1) is deemed a requirement of title XXII of such Act.”.

TITLE XXIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME ¹

PART A—ADMINISTRATION OF RESEARCH PROGRAMS

SEC. 2301. [300cc] REQUIREMENT OF ANNUAL COMPREHENSIVE REPORT ON ALL EXPENDITURES BY SECRETARY WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME.

(a) IN GENERAL.—Not later than December 1 of each fiscal year, the Secretary shall prepare and submit to the Congress a report on the expenditures by the Secretary of amounts appropriated for the preceding fiscal year with respect to acquired immune deficiency syndrome.

(b) INCLUSION OF CERTAIN INFORMATION.—The report required in subsection (a) shall, with respect to acquired immune deficiency syndrome, include—

(1) for each program, project, or activity with respect to such syndrome, a specification of the amount obligated by each office and agency of the Department of Health and Human Services;

(2) a summary description of each such program, project, or activity;

(3) a list of such programs, projects, or activities that are directed towards members of minority groups;

(4) a description of the extent to which programs, projects, and activities described in paragraph (3) have been coordinated between the Director of the Office of Minority Health and the Director of the Centers for Disease Control and Prevention;

(5) a summary of the progress made by each such program, project, or activity with respect to the prevention and control of acquired immune deficiency syndrome;

(6) a summary of the evaluations conducted under this title; and

(7) any report required in this Act to be submitted to the Secretary for inclusion in the report required in subsection (a).

SEC. 2302. [300cc-1] REQUIREMENT OF EXPEDITING AWARDS OF GRANTS AND CONTRACTS FOR RESEARCH.

(a) IN GENERAL.—The Secretary shall expedite the award of grants, contracts, and cooperative agreements for research projects relating to acquired immune deficiency syndrome (including such research projects initiated independently of any solicitation by the Secretary for proposals for such research projects).

(b) TIME LIMITATIONS WITH RESPECT TO CERTAIN APPLICATIONS.—

¹ A National Commission on Acquired Immune Deficiency Syndrome was established by section 242 of Public Law 100-607. Subtitle E of title II of such Public Law established various other authorities regarding acquired immune deficiency syndrome.

(1) With respect to programs of grants, contracts, and cooperative agreements described in subsection (a), any application submitted in response to a solicitation by the Secretary for proposals pursuant to such a program—

(A) may not be approved if the application is submitted after the expiration of the 3-month period beginning on the date on which the solicitation is issued; and

(B) shall be awarded, or otherwise finally acted upon, not later than the expiration of the 6-month period beginning on the expiration of the period described in subparagraph (A).

(2) If the Secretary makes a determination that it is not practicable to administer a program referred to in paragraph (1) in accordance with the time limitations described in such paragraph, the Secretary may adjust the time limitations accordingly.

(c) REQUIREMENTS WITH RESPECT TO ADJUSTMENTS IN TIME LIMITATIONS.—With respect to any program for which a determination described in subsection (b)(2) is made, the Secretary shall—

(1) if the determination is made before the Secretary issues a solicitation for proposals pursuant to the program, ensure that the solicitation describes the time limitations as adjusted by the determination; and

(2) if the determination is made after the Secretary issues such a solicitation for proposals, issue a statement describing the time limitations as adjusted by the determination and individually notify, with respect to the determination, each applicant whose application is submitted before the expiration of the 3-month period beginning on the date on which the solicitation was issued.

(d) ANNUAL REPORTS TO CONGRESS.—Except as provided in subsection (e), the Secretary shall annually prepare, for inclusion in the comprehensive report required in section 2301, a report—

(A)¹ summarizing programs for which the Secretary has made a determination described in subsection (b)(2), including a description of the time limitations as adjusted by the determination and including a summary of the solicitation issued by the Secretary for proposals pursuant to the program; and

(B) summarizing applications that—

(i) were submitted pursuant to a program of grants, contracts, or cooperative agreements referred to in paragraph (1) of subsection (b) for which a determination described in paragraph (2) of such subsection has not been made; and

(ii) were not processed in accordance with the time limitations described in such paragraph (1).

(e) QUARTERLY REPORTS FOR FISCAL YEAR 1989.—For fiscal year 1989, the report required in subsection (d) shall, not less than quarterly, be prepared and submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

¹Designations are so in original. Subparagraphs (A) and (B) should probably be designated paragraphs (1) and (2), respectively. Similarly, clauses (i) and (ii) of subparagraph (B) should probably be designated subparagraphs (A) and (B), respectively.

SEC. 2303. [300cc-2] REQUIREMENTS WITH RESPECT TO PROCESSING OF REQUESTS FOR PERSONNEL AND ADMINISTRATIVE SUPPORT.

(a) **IN GENERAL.**—The Director of the Office of Personnel Management or the Administrator of General Services, as the case may be, shall respond to any priority request made by the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, or the Director of the National Institutes of Health, not later than 21 days after the date on which such request is made. If the Director of the Office of Personnel Management or the Administrator of General Services, as the case may be, does not disapprove a priority request during the 21-day period, the request shall be deemed to be approved.

(b) **NOTICE TO SECRETARY AND TO ASSISTANT SECRETARY FOR HEALTH.**—The Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and the Director of the National Institutes of Health, shall, respectively, transmit to the Secretary and the Assistant Secretary for Health a copy of each priority request made under this section by the agency head involved. The copy shall be transmitted on the date on which the priority request involved is made.

(c) **DEFINITION OF PRIORITY REQUEST.**—For purposes of this section, the term “priority request” means any request that—

(1) is designated as a priority request by the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, or the Director of the National Institutes of Health; and

(2)(A) is made to the Director of the Office of Personnel Management for the allocation of personnel to carry out activities with respect to acquired immune deficiency syndrome; or

(B) is made to the Administrator of General Services for administrative support or space in carrying out such activities.

SEC. 2304. [300cc-3] ESTABLISHMENT OF RESEARCH ADVISORY COMMITTEE.

(a) **IN GENERAL.**—After consultation with the Commissioner of Food and Drugs, the Secretary, acting through the Director of the National Institute of Allergy and Infectious Diseases, shall establish within such Institute an advisory committee to be known as the AIDS Research Advisory Committee (hereafter in this section referred to as the “Committee”).

(b) **COMPOSITION.**—The Committee shall be composed of physicians whose clinical practice includes a significant number of patients with acquired immune deficiency syndrome.

(c) **DUTIES.**—The Committee shall—

(1) advise the Director of such Institute (and may provide advice to the Directors of other agencies of the National Institutes of Health, as appropriate) on appropriate research activities to be undertaken with respect to clinical treatment of such syndrome, including advice with respect to—

(A) research on drugs for preventing or minimizing the development of symptoms or conditions arising from infection with the etiologic agent for such syndrome, including recommendations on the projects of research with respect to diagnosing immune deficiency and with respect to predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases; and

(B) research on the effectiveness of treating such symptoms or conditions with drugs that—

(i) are not approved by the Commissioner of Food and Drugs for the purpose of treating such symptoms or conditions; and

(ii) are being utilized for such purpose by individuals infected with such etiologic agent;

(2)(A) review ongoing publicly and privately supported research on clinical treatment for acquired immune deficiency syndrome, including research on drugs described in paragraph (1); and

(B) periodically issue, and make available to health care professionals, reports describing and evaluating such research;

(3) conduct studies and convene meetings for the purpose of determining the recommendations among physicians in clinical practice on clinical treatment of acquired immune deficiency syndrome, including treatment with the drugs described in paragraph (1); and

(4) conduct a study for the purpose of developing, with respect to individuals infected with the etiologic agent for acquired immune deficiency syndrome, a consensus among health care professionals on clinical treatments for preventing or minimizing the development of symptoms or conditions arising from infection with such etiologic agent.

PART B—RESEARCH AUTHORITY

SEC. 2311. [300cc-11] CLINICAL EVALUATION UNITS AT NATIONAL INSTITUTES OF HEALTH.

(a) IN GENERAL.—The Secretary, acting through the Director of the National Cancer Institute and the Director of the National Institute of Allergy and Infectious Diseases, shall for each such Institute establish a clinical evaluation unit at the Clinical Center at the National Institutes of Health. Each of the clinical evaluation units—

(1) shall conduct clinical evaluations of experimental treatments for acquired immune deficiency syndrome developed within the preclinical drug development program, including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases; and

(2) may conduct clinical evaluations of experimental treatments for such syndrome that are developed by any other national research institute of the National Institutes of Health or by any other entity.

(b) PERSONNEL AND ADMINISTRATIVE SUPPORT.—

(1) For the purposes described in subsection (a), the Secretary, acting through the Director of the National Institutes

of Health, shall provide each of the clinical evaluation units required in such subsection—

(A)(i) with not less than 50 beds; or

(ii) with an outpatient clinical capacity equal to not less than twice the outpatient clinical capacity, with respect to acquired immune deficiency syndrome, possessed by the Clinical Center of the National Institutes of Health on June 1, 1988; and

(B) with such personnel, such administrative support, and such other support services as may be necessary.

(2) Facilities, personnel, administrative support, and other support services provided pursuant to paragraph (1) shall be in addition to the number or level of facilities, personnel, administrative support, and other support services that otherwise would be available at the Clinical Center at the National Institutes of Health for the provision of clinical care for individuals with diseases or disorders.

(c) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 2312. [300cc-12] USE OF INVESTIGATIONAL NEW DRUGS WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME.

(a) **ENCOURAGEMENT OF APPLICATIONS WITH RESPECT TO CLINICAL TRIALS.**—

(1) If, in the determination of the Secretary, there is preliminary evidence that a new drug has effectiveness in humans with respect to the prevention or treatment of acquired immune deficiency syndrome, the Secretary shall, through statements published in the Federal Register—

(A) announce the fact of such determination; and

(B) with respect to the new drug involved, encourage an application for an exemption for investigational use of the new drug under regulations issued under section 505(i) of the Federal Food, Drug, and Cosmetic Act.

(2)(A) The AIDS Research Advisory Committee established pursuant to section 2304 shall make recommendations to the Secretary with respect to new drugs appropriate for determinations described in paragraph (1).

(B) The Secretary shall, as soon as is practicable, determine the merits of recommendations received by the Secretary pursuant to subparagraph (A).

(b) **ENCOURAGEMENT OF APPLICATIONS WITH RESPECT TO TREATMENT USE IN CIRCUMSTANCES OTHER THAN CLINICAL TRIALS.**—

(1) In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a) and with respect to which an exemption is in effect for purposes of section 505(i) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall—

(A) as appropriate, encourage the sponsor of the investigation of the new drug to submit to the Secretary, in accordance with regulations issued under such section, an application to use the drug in the treatment of individuals—

(i) who are infected with the etiologic agent for acquired immune deficiency syndrome; and

(ii) who are not participating in the clinical trials conducted pursuant to such exemption; and

(B) if such an application is approved, encourage, as appropriate, licensed medical practitioners to obtain, in accordance with such regulations, the new drug from such sponsor for the purpose of treating such individuals.

(2) If the sponsor of the investigation of a new drug described in paragraph (1) does not submit to the Secretary an application described in such paragraph (relating to treatment use), the Secretary shall, through statements published in the Federal Register, encourage, as appropriate, licensed medical practitioners to submit to the Secretary such applications in accordance with regulations described in such paragraph.

(c) **TECHNICAL ASSISTANCE WITH RESPECT TO TREATMENT USE.**—In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a), the Secretary may, directly or through grants or contracts, provide technical assistance with respect to the process of—

(1) submitting to the Secretary applications for exemptions described in paragraph (1)(B) of such subsection;

(2) submitting to the Secretary applications described in subsection (b); and

(3) with respect to sponsors of investigations of new drugs, facilitating the transfer of new drugs from such sponsors to licensed medical practitioners.

(d) **DEFINITION.**—For purposes of this section, the term “new drug” has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act.

SEC. 2313. [300cc-13] TERRY BEIRN COMMUNITY-BASED AIDS RESEARCH INITIATIVE.

(a) **IN GENERAL.**—After consultation with the Commissioner of Food and Drugs, the Director of the National Institutes of Health, acting through the National Institute¹ of Allergy and Infectious Diseases, may make grants to public entities and nonprofit private entities concerned with acquired immune deficiency syndrome, and may enter into contracts with public and private such entities, for the purpose of planning and conducting, in the community involved, clinical trials of experimental treatments for infection with the etiologic agent for such syndrome that are approved by the Commissioner of Food and Drugs for investigational use under regulations issued under section 505 of the Federal Food, Drug, and Cosmetic Act.

(b) **REQUIREMENT OF CERTAIN PROJECTS.**—

(1) Financial assistance under subsection (a) shall include such assistance to community-based organizations and community health centers for the purpose of—

(A) retaining appropriate medical supervision;

¹ So in original. Probably should be “acting through the Director of the National Institute”. (Section 2617(b)(1) of Public Law 100-690 expressed the intent to so amend the provision; however, the amendment cannot be executed because the amendatory instructions are to strike “through the National Institutes of Allergy”, and this term does not appear in subsection (a) (above).)

(B) assisting with administration, data collection and record management; and

(C) conducting training of community physicians, nurse practitioners, physicians' assistants and other health professionals for the purpose of conducting clinical trials.

(2)(A) Financial assistance under subsection (a) shall include such assistance for demonstration projects designed to implement and conduct community-based clinical trials in order to provide access to the entire scope of communities affected by infections with the etiologic agent for acquired immune deficiency syndrome, including minorities, hemophiliacs and transfusion-exposed individuals, women, children, users of intravenous drugs, and individuals who are asymptomatic with respect to such infection.

(B) The Director of the National Institutes of Health may not provide financial assistance under this paragraph unless the application for such assistance is approved—

(i) by the Commissioner of Food and Drugs;

(ii) by a duly constituted Institutional Review Board that meets the requirements of part 56 of title 21, Code of Federal Regulations; and

(iii) by the Director of the National Institute of Allergy and Infectious Diseases.

(c) PARTICIPATION OF PRIVATE INDUSTRY, SCHOOLS OF MEDICINE AND PRIMARY PROVIDERS.—Programs carried out with financial assistance provided under subsection (a) shall be designed to encourage private industry and schools of medicine, osteopathic medicine, and existing consortia of primary care providers organized to conduct clinical research concerning acquired immune deficiency syndrome to participate in, and to support, the clinical trials conducted pursuant to the programs.

(d) REQUIREMENT OF APPLICATION.—The Secretary may not provide financial assistance under subsection (a) unless—

(1) an application for the assistance is submitted to the Secretary;

(2) with respect to carrying out the purpose for which the assistance is to be made, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) For the purpose of carrying out subsection (b)(1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1996.

(2) For the purpose of carrying out subsection (b)(2), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1996.

SEC. 2314. [300cc-14] EVALUATION OF CERTAIN TREATMENTS.

(a) ESTABLISHMENT OF PROGRAM.—

(1) After consultation with the AIDS Research Advisory Committee established pursuant to section 2304, the Secretary shall establish a program for the evaluation of drugs that—

(A) are not approved by the Commissioner of Food and Drugs for the purpose of treatments with respect to acquired immune deficiency syndrome; and

(B) are being utilized for such purpose by individuals infected with the etiologic agent for such syndrome.

(2) The program established under paragraph (1) shall include evaluations of the effectiveness and the risks of the treatment involved, including the risks of foregoing treatments with respect to acquired immune deficiency syndrome that are approved by the Commissioner of Food and Drugs.

(b) **AUTHORITY WITH RESPECT TO GRANTS AND CONTRACTS.—**

(1) For the purpose of conducting evaluations required in subsection (a), the Secretary may make grants to, and enter into cooperative agreements and contracts with, public and nonprofit private entities.

(2) Nonprofit private entities under paragraph (1) may include nonprofit private organizations that—

(A) are established for the purpose of evaluating treatments with respect to acquired immune deficiency syndrome; and

(B) consist primarily of individuals infected with the etiologic agent for such syndrome.

(c) **SCIENTIFIC AND ETHICAL GUIDELINES.—**

(1) The Secretary shall establish appropriate scientific and ethical guidelines for the conduct of evaluations carried out pursuant to this section. The Secretary may not provide financial assistance under subsection (b)(1) unless the applicant for such assistance agrees to comply with such guidelines.

(2) The Secretary may establish the guidelines described in paragraph (1) only after consulting with—

(A) physicians whose clinical practice includes a significant number of individuals with acquired immune deficiency syndrome;

(B) individuals who are infected with the etiologic agent for such syndrome; and

(C) other individuals with appropriate expertise or experience.

(d) **AUTHORIZATION OF APPROPRIATIONS.—**For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 2315. [300cc-15] SUPPORT OF INTERNATIONAL EFFORTS.

(a) **GRANTS AND CONTRACTS FOR RESEARCH.—**

(1) Under section 307, the Secretary, acting through the Director of the National Institutes of Health—

(A) shall, for the purpose described in paragraph (2), make grants to, enter into cooperative agreements and contracts with, and provide technical assistance to, international organizations concerned with public health; and

(B) may, for such purpose, provide technical assistance to foreign governments.

(2) The purpose referred to in paragraph (1) is promoting and expediting international research and training concerning the natural history and pathogenesis of the human immunodeficiency virus and the development and evaluation of vaccines and treatments for acquired immune deficiency syndrome and opportunistic infections.

(b) GRANTS AND CONTRACTS FOR ADDITIONAL PURPOSES.—After consultation with the Administrator of the Agency for International Development, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall under section 307 make grants to, enter into contracts with, and provide technical assistance to, international organizations concerned with public health and may provide technical assistance to foreign governments, in order to support—

(1) projects for training individuals with respect to developing skills and technical expertise for use in the prevention, diagnosis, and treatment of acquired immune deficiency syndrome; and

(2) epidemiological research relating to acquired immune deficiency syndrome.

(c) SPECIAL PROGRAMME OF WORLD HEALTH ORGANIZATION.—Support provided by the Secretary pursuant to this section shall be in furtherance of the global strategy of the World Health Organization Special Programme on Acquired Immunodeficiency Syndrome.

(d) PREFERENCES.—In providing grants, cooperative agreements, contracts, and technical assistance under subsections (a) and (b), the Secretary shall—

(1) give preference to activities under such subsections conducted by, or in cooperation with, the World Health Organization; and

(2) with respect to activities carried out under such subsections in the Western Hemisphere, give preference to activities conducted by, or in cooperation with, the Pan American Health Organization or the World Health Organization.

(e) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant or enter into a cooperative agreement or contract under this section unless—

(1) an application for such assistance is submitted to the Secretary;

(2) with respect to carrying out the purpose for which such assistance is to be provided, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

SEC. 2316. [300cc-16] RESEARCH CENTERS.

(a) IN GENERAL.—

(1) The Secretary, acting through the Director of the National Institute of Allergy and Infectious Diseases, may

make grants to, and enter into contracts with, public and non-profit private entities to assist such entities in planning, establishing, or strengthening, and providing basic operating support for, centers for basic and clinical research into, and training in, advanced diagnostic, prevention, and treatment methods for acquired immune deficiency syndrome.

(2) A grant or contract under paragraph (1) shall be provided in accordance with policies established by the Secretary, acting through the Director of the National Institutes of Health, and after consultation with the advisory council for the National Institute of Allergy and Infectious Diseases.

(3) The Secretary shall ensure that, as appropriate, clinical research programs carried out under paragraph (1) include as research subjects women, children, hemophiliacs, and minorities.

(b) USE OF FINANCIAL ASSISTANCE.—

(1) Financial assistance under subsection (a) may be expended for—

(A) the renovation or leasing of space;

(B) staffing and other basic operating costs, including such patient care costs as are required for clinical research;

(C) clinical training with respect to acquired immune deficiency syndrome (including such training for allied health professionals); and

(D) demonstration purposes, including projects in the long-term monitoring and outpatient treatment of individuals infected with the etiologic agent for such syndrome.

(2) Financial assistance under subsection (a) may not be expended to provide research training for which National Research Service Awards may be provided under section 487.

(c) DURATION OF SUPPORT.—Support of a center under subsection (a) may be for not more than five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 2317. [300cc-17] INFORMATION SERVICES.

(a) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish, maintain, and operate a program with respect to information on research, treatment, and prevention activities relating to infection with the etiologic agent for acquired immune deficiency syndrome. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated.

(b) TOLL-FREE TELEPHONE COMMUNICATIONS FOR HEALTH CARE ENTITIES.—

(1) After consultation with the Director of the Office of AIDS Research, the Administrator of the Health Resources and

Services Administration, and the Director of the Centers for Disease Control and Prevention, the Secretary shall provide for toll-free telephone communications to provide medical and technical information with respect to acquired immune deficiency syndrome to health care professionals, allied health care providers, and to professionals providing emergency health services.

(2) Information provided pursuant to paragraph (1) shall include—

(A) information on prevention of exposure to, and the transmission of, the etiologic agent for acquired immune deficiency syndrome; and

(B) information contained in the data banks established in subsections (c) and (d).

(c) DATA BANK ON RESEARCH INFORMATION.—

(1) After consultation with the Director of the Office of AIDS Research, the Director of the Centers for Disease Control and Prevention, and the National Library of Medicine, the Secretary shall establish a data bank of information on the results of research with respect to acquired immune deficiency syndrome conducted in the United States and other countries.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. To the extent practicable, the Secretary shall make such information available to researchers, physicians, and other appropriate individuals, of countries other than the United States.

(d) DATA BANK ON CLINICAL TRIALS AND TREATMENTS.—

(1) After consultation with the Commissioner of Food and Drugs, the AIDS Research Advisory Committee established under section 2304, and the Director of the Office of AIDS Research, the Secretary shall, in carrying out subsection (a), establish a data bank of information on clinical trials and treatments with respect to infection with the etiologic agent for acquired immune deficiency syndrome (hereafter in this section referred to as the "Data Bank").

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems available to individuals infected with the etiologic agent for acquired immune deficiency syndrome, to other members of the public, to health care providers, and to researchers.

(e) REQUIREMENTS WITH RESPECT TO DATA BANK ON CLINICAL TRIALS AND TREATMENTS.—The Data Bank shall include the following:

(1) A registry of clinical trials of experimental treatments for acquired immune deficiency syndrome and related illnesses conducted under regulations promulgated pursuant to section 505 of the Federal Food, Drug and Cosmetic Act that provides a description of the purpose of each experimental drug protocol either with the consent of the protocol sponsor, or when a trial to test efficacy begins. Information provided shall include eligibility criteria and the location of trial sites, and must be

forwarded to the Data Bank by the sponsor of the trial not later than 21 days after the approval by the Food and Drug Administration.

(2) Information pertaining to experimental treatments for acquired immune deficiency syndrome that may be available under a treatment investigational new drug application that has been submitted to the Food and Drug Administration pursuant to part 312 of title 21, Code of Federal Regulations. The Data Bank shall also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, of such experimental treatments, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatment.

SEC. 2318. [300cc-18] DEVELOPMENT OF MODEL PROTOCOLS FOR CLINICAL CARE OF INFECTED INDIVIDUALS.

(a) IN GENERAL.—

(1) The Secretary, acting through the Director of the National Institutes of Health and after consultation with the Administrator for Health Care Policy and Research, may make grants to public and nonprofit private entities for the establishment of projects to develop model protocols for the clinical care of individuals infected with the etiologic agent for acquired immune deficiency syndrome, including treatment and prevention of HIV infection and related conditions among women.

(2) The Secretary may not make a grant under paragraph

(1) unless—

(A) the applicant for the grant is a provider of comprehensive primary care; or

(B) the applicant for the grant agrees, with respect to the project carried out pursuant to paragraph (1), to enter into a cooperative arrangement with an entity that is a provider of comprehensive primary care.

(b) REQUIREMENT OF PROVISION OF CERTAIN SERVICES.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, with respect to patients participating in the project carried out with the grant, services provided pursuant to the grant will include—

(1) monitoring, in clinical laboratories, of the condition of such patients;

(2) clinical intervention for infection with the etiologic agent for acquired immune deficiency syndrome, including measures for the prevention of conditions arising from the infection;

(3) information and counseling on the availability of treatments for such infection approved by the Commissioner of Food and Drugs, on the availability of treatments for such infection not yet approved by the Commissioner, and on the reports issued by the AIDS Research Advisory Committee under section 2304(c)(2)(B);

(4) support groups; and

(5) information on, and referrals to, entities providing appropriate social support services.

(c) **LIMITATION ON IMPOSITION OF CHARGES FOR SERVICES.**—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, if the applicant will routinely impose a charge for providing services pursuant to the grant, the applicant will not impose the charge on any individual seeking such services who is unable to pay the charge.

(d) **EVALUATION AND REPORTS.**—

(1) The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees, with respect to the project carried out pursuant to subsection (a), to submit to the Secretary—

(A) information sufficient to assist in the replication of the model protocol developed pursuant to the project; and

(B) such reports as the Secretary may require.

(2) The Secretary shall provide for evaluations of projects carried out pursuant to subsection (a) and shall annually submit to the Congress a report describing such projects. The report shall include the findings made as a result of such evaluations and may include any recommendations of the Secretary for appropriate administrative and legislative initiatives with respect to the program established in this section.

(e) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1991, and such sums as may be necessary for each of the fiscal years 1994 through 1996.

SEC. 2319. [300cc-19] NATIONAL BLOOD RESOURCE EDUCATION PROGRAM.

After consultation with the Director of the National Heart, Lung, and Blood Institute and the Commissioner of Food and Drugs, the Secretary shall establish a program of research and education regarding blood donations and transfusions to maintain and improve the safety of the blood supply. Education programs shall be directed at health professionals, patients, and the community to—

(1) in the case of the public and patients undergoing treatment—

(A) increase awareness that the process of donating blood is safe;

(B) promote the concept that blood donors are contributors to a national need to maintain an adequate and safe blood supply;

(C) encourage blood donors to donate more than once a year; and

(D) encourage repeat blood donors to recruit new donors;

(2) in the case of health professionals—

(A) improve knowledge, attitudes, and skills of health professionals in the appropriate use of blood and blood components;

(B) increase the awareness and understanding of health professionals regarding the risks versus benefits of blood transfusion; and

(C) encourage health professionals to consider alternatives to the administration of blood or blood components for their patients; and

(3) in the case of the community, increase coordination, communication, and collaboration among community, professional, industry, and government organizations regarding blood donation and transfusion issues.

SEC. 2320. [300cc-20] ADDITIONAL AUTHORITY WITH RESPECT TO RESEARCH.

(a) DATA COLLECTION WITH RESPECT TO NATIONAL PREVALENCE.—

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, through representative sampling and other appropriate methodologies, provide for the continuous collection of data on the incidence in the United States of cases of acquired immune deficiency syndrome and of cases of infection with the etiologic agent for such syndrome. The Secretary may carry out the program of data collection directly or through cooperative agreements and contracts with public and nonprofit private entities.

(2) The Secretary shall encourage each State to enter into a cooperative agreement or contract under paragraph (1) with the Secretary in order to facilitate the prompt collection of the most recent accurate data on the incidence of cases described in such paragraph.

(3) The Secretary shall ensure that data collected under paragraph (1) includes data on the demographic characteristics of the population of individuals with cases described in paragraph (1), including data on specific subpopulations at risk of infection with the etiologic agent for acquired immune deficiency syndrome.

(4) In carrying out this subsection, the Secretary shall, for the purpose of assuring the utility of data collected under this section, request entities with expertise in the methodologies of data collection to provide, as soon as is practicable, assistance to the Secretary and to the States with respect to the development and utilization of uniform methodologies of data collection.

(5) The Secretary shall provide for the dissemination of data collected pursuant to this subsection. In carrying out this paragraph, the Secretary may publish such data as frequently as the Secretary determines to be appropriate with respect to the protection of the public health. The Secretary shall publish such data not less than once each year.

(b) EPIDEMIOLOGICAL AND DEMOGRAPHIC DATA.—

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop an epidemiological data base and shall provide for long-term studies for the purposes of—

(A) collecting information on the demographic characteristics of the population of individuals infected with the etiologic agent for acquired immune deficiency syndrome and the natural history of such infection; and

(B) developing models demonstrating the long-term domestic and international patterns of the transmission of such etiologic agent.

(2) The Secretary may carry out paragraph (1) directly or through grants to, or cooperative agreements¹ or contracts with, public and nonprofit private entities, including Federal agencies.

(c) LONG-TERM RESEARCH.—The Secretary may make grants to public and nonprofit private entities for the purpose of assisting grantees in conducting long-term research into treatments for acquired immune deficiency syndrome developed from knowledge of the genetic nature of the etiologic agent for such syndrome.

(d) SOCIAL SCIENCES RESEARCH.—The Secretary, acting through the Director of the National Institute of Mental Health, may make grants to public and nonprofit private entities for the purpose of assisting grantees in conducting scientific research into the psychological and social sciences as such sciences relate to acquired immune deficiency syndrome.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

(2) Amounts appropriated pursuant to paragraph (1) to carry out subsection (c) shall remain available until expended.

PART C—RESEARCH TRAINING

SEC. 2341. [300cc-31] FELLOWSHIPS AND TRAINING.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control², shall establish fellowship and training programs to be conducted by the Centers for Disease Control² to train individuals to develop skills in epidemiology, surveillance, testing, counseling, education, information, and laboratory analysis relating to acquired immune deficiency syndrome. Such programs shall be designed to enable health professionals and health personnel trained under such programs to work, after receiving such training, in national and international efforts toward the prevention, diagnosis, and treatment of acquired immune deficiency syndrome.

(b) PROGRAMS CONDUCTED BY NATIONAL INSTITUTE OF MENTAL HEALTH.—The Secretary, acting through the Director of the National Institute of Mental Health, shall conduct or support fellowship and training programs for individuals pursuing graduate or postgraduate study in order to train such individuals to conduct scientific research into the psychological and social sciences as such sciences relate to acquired immune deficiency syndrome.

(c) RELATIONSHIP TO LIMITATION ON NUMBER OF EMPLOYEES.—Any individual receiving a fellowship or receiving training under subsection (a) or (b) shall not be included in any determination of the number of full-time equivalent employees of the Department of

¹ So in law. Probably should be "agreements".

² So in law. Section 312(d)(21) of Public Law 102-531 (106 Stat. 3505) provided that section 2341(a) is amended by striking "Centers for Disease Control" and inserting "Centers for Disease Control and Prevention". The amendment cannot be executed because it does not specify to which of the instances of such term the amendment applies.

Health and Human Services for the purpose of any limitation on the number of such employees established by law prior to, on, or after the date of the enactment of the AIDS Amendments of 1988.

(d) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

PART D—OFFICE OF AIDS RESEARCH

Subpart I—Interagency Coordination of Activities

SEC. 2351. [300cc-40] ESTABLISHMENT OF OFFICE.

(a) **IN GENERAL.**—There is established within the National Institutes of Health an office to be known as the Office of AIDS Research. The Office shall be headed by a director, who shall be appointed by the Secretary.

(b) DUTIES.—

(1) **INTERAGENCY COORDINATION OF AIDS ACTIVITIES.**—With respect to acquired immune deficiency syndrome, the Director of the Office shall plan, coordinate, and evaluate research and other activities conducted or supported by the agencies of the National Institutes of Health. In carrying out the preceding sentence, the Director of the Office shall evaluate the AIDS activities of each of such agencies and shall provide for the periodic reevaluation of such activities.

(2) **CONSULTATIONS.**—The Director of the Office shall carry out this subpart (including developing and revising the plan required in section 2353) in consultation with the heads of the agencies of the National Institutes of Health, with the advisory councils of the agencies, and with the advisory council established under section 2352.

(3) **COORDINATION.**—The Director of the Office shall act as the primary Federal official with responsibility for overseeing all AIDS research conducted or supported by the National Institutes of Health, and

(A) shall serve to represent the National Institutes of Health AIDS Research Program at all relevant Executive branch task forces and committees; and

(B) shall maintain communications with all relevant Public Health Service agencies and with various other departments of the Federal Government, to ensure the timely transmission of information concerning advances in AIDS research and the clinical treatment of acquired immune deficiency syndrome and its related conditions, between these various agencies for dissemination to affected communities and health care providers.

SEC. 2352. [300cc-40a] ADVISORY COUNCIL; COORDINATING COMMITTEES.

(a) ADVISORY COUNCIL.—

(1) **IN GENERAL.**—The Secretary shall establish an advisory council for the purpose of providing advice to the Director of the Office on carrying out this part. (Such council is referred to in this subsection as the “Advisory Council”).

(2) COMPOSITION, COMPENSATION, TERMS, CHAIR, ETC.—Subsections (b) through (g) of section 406 apply to the Advisory Council to the same extent and in the same manner as such subsections apply to advisory councils for the national research institutes, except that—

(A) in addition to the ex officio members specified in section 406(b)(2), there shall serve as such members of the Advisory Council a representative from the advisory council of each of the National Cancer Institute and the National Institute on Allergy and Infectious Diseases; and

(B) with respect to the other national research institutes, there shall serve as ex officio members of such Council, in addition to such members specified in subparagraph (A), a representative from the advisory council of each of the 2 institutes that receive the greatest funding for AIDS activities.

(b) INDIVIDUAL COORDINATING COMMITTEES REGARDING RESEARCH DISCIPLINES.—

(1) IN GENERAL.—The Director of the Office shall establish, for each research discipline in which any activity under the plan required in section 2353 is carried out, a committee for the purpose of providing advice to the Director of the Office on carrying out this part with respect to such discipline. (Each such committee is referred to in this subsection as a “coordinating committee”).

(2) COMPOSITION.—Each coordinating committee shall be composed of representatives of the agencies of the National Institutes of Health with significant responsibilities regarding the research discipline involved.

SEC. 2353. [300cc-40b] COMPREHENSIVE PLAN FOR EXPENDITURE OF APPROPRIATIONS.

(a) IN GENERAL.—Subject to the provisions of this section and other applicable law, the Director of the Office, in carrying out section 2351, shall—

(1) establish a comprehensive plan for the conduct and support of all AIDS activities of the agencies of the National Institutes of Health (which plan shall be first established under this paragraph not later than 12 months after the date of the enactment of the National Institutes of Health Revitalization Act of 1993);¹

(2) ensure that the Plan establishes priorities among the AIDS activities that such agencies are authorized to carry out;

(3) ensure that the Plan establishes objectives regarding such activities, describes the means for achieving the objectives, and designates the date by which the objectives are expected to be achieved;

(4) ensure that all amounts appropriated for such activities are expended in accordance with the Plan;

(5) review the Plan not less than annually, and revise the Plan as appropriate; and

(6) ensure that the Plan serves as a broad, binding statement of policies regarding AIDS activities of the agencies, but

¹Enacted June 10, 1993.

does not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other details of the daily administration of such activities, in accordance with the Plan.

(b) CERTAIN COMPONENTS OF PLAN.—With respect to AIDS activities of the agencies of the National Institutes of Health, the Director of the Office shall ensure that the Plan—

- (1) provides for basic research;
- (2) provides for applied research;
- (3) provides for research that is conducted by the agencies;
- (4) provides for research that is supported by the agencies;
- (5) provides for proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and
- (6) provides for behavioral research and social sciences research.

(c) BUDGET ESTIMATES.—

(1) FULL-FUNDING BUDGET.—

(A) With respect to a fiscal year, the Director of the Office shall prepare and submit directly to the President, for review and transmittal to the Congress, a budget estimate for carrying out the Plan for the fiscal year, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the advisory council established under section 2352. The budget estimate shall include an estimate of the number and type of personnel needs for the Office.

(B) The budget estimate submitted under subparagraph (A) shall estimate the amounts necessary for the agencies of the National Institutes of Health to carry out all AIDS activities determined by the Director of the Office to be appropriate, without regard to the probability that such amounts will be appropriated.

(2) ALTERNATIVE BUDGETS.—

(A) With respect to a fiscal year, the Director of the Office shall prepare and submit to the Secretary and the Director of the National Institutes of Health the budget estimates described in subparagraph (B) for carrying out the Plan for the fiscal year. The Secretary and such Director shall consider each of such estimates in making recommendations to the President regarding a budget for the Plan for such year.

(B) With respect to the fiscal year involved, the budget estimates referred to in subparagraph (A) for the Plan are as follows:

(i) The budget estimate submitted under paragraph (1).

(ii) A budget estimate developed on the assumption that the amounts appropriated will be sufficient only for—

(I) continuing the conduct by the agencies of the National Institutes of Health of existing AIDS activities (if approved for continuation), and continuing the support of such activities by the agen-

cies in the case of projects or programs for which the agencies have made a commitment of continued support; and

(II) carrying out, of activities that are in addition to activities specified in subclause (I), only such activities for which the Director determines there is the most substantial need.

(iii) Such other budget estimates as the Director of the Office determines to be appropriate.

(d) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out AIDS activities under the Plan, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

(2) RECEIPT OF FUNDS.—For the first fiscal year beginning after the date on which the Plan first established under section 2353(a)(1) has been in effect for 12 months, and for each subsequent fiscal year, the Director of the Office shall receive directly from the President and the Director of the Office of Management and Budget all funds available for AIDS activities of the National Institutes of Health.

(3) ALLOCATIONS FOR AGENCIES.—

(A) Each fiscal year the Director of the Office shall, from the amounts received under paragraph (2) for the fiscal year, allocate to the agencies of the National Institutes of Health (in accordance with the Plan) all amounts available for such year for carrying out the AIDS activities specified in subsection (c)(2)(B)(ii)(I) for such year. Such allocation shall, to the extent practicable, be made not later than 15 days after the date on which the Director receives amounts under paragraph (2).

(B) Each fiscal year the Director of the Office shall, from the amounts received under paragraph (2) for the fiscal year, allocate to the agencies of the National Institutes of Health (in accordance with the Plan) all amounts available for such year for carrying out AIDS activities that are not referred to in subparagraph (A). Such allocation shall, to the extent practicable, be made not later than 30 days after the date on which the Director receives amounts under paragraph (2).

SEC. 2354. [300cc-41] ADDITIONAL AUTHORITIES.

(a) IN GENERAL.—In carrying out AIDS research, the Director of the Office—

(1) shall develop and expand clinical trials of treatments and therapies for infection with the etiologic agent for acquired immune deficiency syndrome, including such clinical trials for women, infants, children, hemophiliacs, and minorities;

(2) may establish or support the large-scale development and preclinical screening, production, or distribution of specialized biological materials and other therapeutic substances for AIDS research and set standards of safety and care for persons using such materials;

(3) may support—

(A) AIDS research conducted outside the United States by qualified foreign professionals if such research can reasonably be expected to benefit the people of the United States;

(B) collaborative research involving American and foreign participants; and

(C) the training of American scientists abroad and foreign scientists in the United States;

(4) may encourage and coordinate AIDS research conducted by any industrial concern that evidences a particular capability for the conduct of such research;

(5)(A) may acquire, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director of the Office determines necessary;

(B) may make grants for the construction or renovation of facilities; and

(C) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34) by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the National Institutes of Health for a period not to exceed ten years; and

(6) subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), may enter into such contracts and cooperative agreements with any public agency, or with any person, firm, association, corporation, or educational institution, as may be necessary to expedite and coordinate research relating to acquired immune deficiency syndrome.

(b) REPORT TO SECRETARY.—The Director of the Office shall each fiscal year prepare and submit to the Secretary, for inclusion in the comprehensive report required in section 2301(a), a report—

(1) describing and evaluating the progress made in such fiscal year in research, treatment, and training with respect to acquired immune deficiency syndrome conducted or supported by the Institutes;

(2) summarizing and analyzing expenditures made in such fiscal year for activities with respect to acquired immune deficiency syndrome conducted or supported by the National Institutes of Health; and

(3) containing such recommendations as the Director considers appropriate.

(c) PROJECTS FOR COOPERATION AMONG PUBLIC AND PRIVATE HEALTH ENTITIES.—In carrying out subsection (a), the Director of the Office shall establish projects to promote cooperation among Federal agencies, State, local, and regional public health agencies, and private entities, in research concerning the diagnosis, prevention, and treatment of acquired immune deficiency syndrome.

Subpart II—Emergency Discretionary Fund

SEC. 2356. [300cc-43] EMERGENCY DISCRETIONARY FUND.

(a) IN GENERAL.—

(1) **ESTABLISHMENT.**—There is established a fund consisting of such amounts as may be appropriated under subsection (g). Subject to the provisions of this section, the Director of the Office, after consultation with the advisory council established under section 2352, may expend amounts in the Fund for the purpose of conducting and supporting such AIDS activities, including projects of AIDS research, as may be authorized in this Act for the National Institutes of Health.

(2) **PRECONDITIONS TO USE OF FUND.**—Amounts in the Fund may be expended only if—

(A) the Director identifies the particular set of AIDS activities for which such amounts are to be expended;

(B) the set of activities so identified constitutes either a new project or additional AIDS activities for an existing project;

(C) the Director of the Office has made a determination that there is a significant need for such set of activities; and

(D) as of June 30 of the fiscal year preceding the fiscal year in which the determination is made, such need was not provided for in any appropriations Act passed by the House of Representatives to make appropriations for the Departments of Labor, Health and Human Services (including the National Institutes of Health), Education, and related agencies for the fiscal year in which the determination is made.

(3) **TWO-YEAR USE OF FUND FOR PROJECT INVOLVED.**—In the case of an identified set of AIDS activities, obligations of amounts in the Fund may not be made for such set of activities after the expiration of the 2-year period beginning on the date on which the initial obligation of such amounts is made for such set.

(b) **PEER REVIEW.**—With respect to an identified set of AIDS activities carried out with amounts in the Fund, this section may not be construed as waiving applicable requirements for peer review.

(c) **LIMITATIONS ON USE OF FUND.**—

(1) **CONSTRUCTION OF FACILITIES.**—Amounts in the Fund may not be used for the construction, renovation, or relocation of facilities, or for the acquisition of land.

(2) **CONGRESSIONAL DISAPPROVAL OF PROJECTS.**—

(A) Amounts in the Fund may not be expended for the fiscal year involved for an identified set of AIDS activities, or a category of AIDS activities, for which—

(i) amounts were made available in an appropriations Act for the preceding fiscal year; and

(ii) amounts are not made available in any appropriations Act for the fiscal year involved; or

(ii) amounts are by law prohibited from being expended.

(B) A determination under subparagraph (A)(i) of whether amounts have been made available in appropriations Acts for a fiscal year shall be made without regard

to whether such Acts make available amounts for the Fund.

(3) INVESTMENT OF FUND AMOUNTS.—Amounts in the Fund may not be invested.

(d) APPLICABILITY OF LIMITATION REGARDING NUMBER OF EMPLOYEES.—The purposes for which amounts in the Fund may be expended include the employment of individuals necessary to carry out identified sets of AIDS activities approved under subsection (a). Any individual employed under the preceding sentence may not be included in any determination of the number of full-time equivalent employees for the Department of Health and Human Services for the purpose of any limitation on the number of such employees established by law prior to, on, or after the date of the enactment of the National Institutes of Health Revitalization Act of 1993.¹

(e) REPORT TO CONGRESS.—Not later than February 1 of each fiscal year, the Director of the Office shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report on the identified sets of AIDS activities carried out during the preceding fiscal year with amounts in the Fund. The report shall provide a description of each such set of activities and an explanation of the reasons underlying the use of the Fund for the set.

(f) DEFINITIONS.—For purposes of this section:

(1) The term “Fund” means the fund established in subsection (a).

(2) The term “identified set of AIDS activities” means a particular set of AIDS activities identified under subsection (a)(2)(A).

(g) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing amounts for the Fund, there is authorized to be appropriated \$100,000,000 for each of the fiscal years 1994 through 1996.

(2) AVAILABILITY.—Amounts appropriated for the Fund are available until expended.

Subpart III—General Provisions

SEC. 2359. [300cc-45] GENERAL PROVISIONS REGARDING THE OFFICE.

(a) ADMINISTRATIVE SUPPORT FOR OFFICE.—The Secretary, acting through the Director of the National Institutes of Health, shall provide administrative support and support services to the Director of the Office and shall ensure that such support takes maximum advantage of existing administrative structures at the agencies of the National Institutes of Health.

(b) EVALUATION AND REPORT.—

(1) EVALUATION.—Not later than 5 years after the date of the enactment of National Institutes of Health Revitalization Act of 1993,¹ the Secretary shall conduct an evaluation to—

(A) determine the effect of this section on the planning and coordination of the AIDS research programs at the in-

¹ Enacted June 10, 1993.

stitutes, centers and divisions of the National Institutes of Health;

(B) evaluate the extent to which this part has eliminated the duplication of administrative resources among such Institutes, centers and divisions; and

(C) provide recommendations concerning future alterations with respect to this part.

(2) REPORT.—Not later than 1 year after the date on which the evaluation is commenced under paragraph (1), the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report concerning the results of such evaluation.

(c) DEFINITIONS.—For purposes of this part:

(1) The term “AIDS activities” means AIDS research and other activities that relate to acquired immune deficiency syndrome.

(2) The term “AIDS research” means research with respect to acquired immune deficiency syndrome.

(3) The term “Office” means the Office of AIDS Research.

(4) The term “Plan” means the plan required in section 2353(a)(1).

PART E—GENERAL PROVISIONS

SEC. 2361. [300cc-51] DEFINITION.

For purposes of this title:

(1) The term “infection”, with respect to the etiologic agent for acquired immune deficiency syndrome, includes opportunistic cancers and infectious diseases and any other conditions arising from infection with such etiologic agent.

(2) The term “treatment”, with respect to the etiologic agent for acquired immune deficiency syndrome, includes primary and secondary prophylaxis.

TITLE XXIV—HEALTH SERVICES WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME ¹

PART A—FORMULA GRANTS TO STATES FOR HOME AND COMMUNITY- BASED HEALTH SERVICES

SEC. 2401. [300dd] ESTABLISHMENT OF PROGRAM.

(a) ALLOTMENTS FOR STATES.—For the purpose described in subsection (b), the Secretary shall for each of the fiscal years 1989 and 1990 make an allotment for each State in an amount determined in accordance with section 2408. The Secretary shall make payments each such fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 2407.

(b) PURPOSE OF GRANTS.—The Secretary may not make payments under subsection (a) for a fiscal year unless the State involved agrees to expend the payments only for the purpose of providing services in accordance with section 2402.

(c) ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this part:

(1) The term “eligible individual” means an individual infected with the etiologic agent for acquired immune deficiency syndrome who either is medically dependent or chronically dependent.

(2) The term “medically dependent” means, with respect to an individual, that the individual has been certified by a physician as—

(A) requiring the routine use of appropriate medical services (which may include home intravenous drug therapy) to prevent or compensate for the individual’s serious deterioration, arising from infection with the etiologic agent for acquired immune deficiency syndrome, of physical health or cognitive function, and

(B) being able to avoid long-term or repeated care as an inpatient or resident in a hospital, nursing facility, or other institution if home and community-based health services are provided to the individual.

(3) The term “chronically dependent” means, with respect to an individual, that the individual has been certified by a physician as—

(A) being unable to perform, because of physical or cognitive impairment (without substantial assistance from another individual) arising from infection with the etiologic agent for acquired immune deficiency syndrome, at least 2 of the following activities of daily living: bathing, dressing, toileting, transferring, and eating, or

¹ See footnote 1 on page 794.

(B) having a similar level of disability due to cognitive impairment (as defined by the Secretary).

(d) HOME AND COMMUNITY-BASED HEALTH SERVICES DEFINED.—For purposes of this part, the term “home and community-based health services”—

(1) means, with respect to an eligible individual, skilled health services furnished to the individual in the individual's home pursuant to a written plan of care established by a health care professional for the provision of such services and items and services described in paragraph (2);

(2) includes—

(A) durable medical equipment,

(B) homemaker/home health aide services and personal care services furnished in the individual's home,

(C) day treatment or other partial hospitalization services,

(D) home intravenous drug therapy (including prescription drugs administered intravenously as part of such therapy), and

(E) routine diagnostic tests administered in the individual's home,
furnished pursuant to such plan of care; but

(3) does not include, except as specifically provided in paragraph (2)—

(A) diagnostic tests,

(B) inpatient hospital services,

(C) nursing facility services, and

(D) prescription drugs.

SEC. 2402. [300dd-1] PROVISIONS WITH RESPECT TO CARRYING OUT PURPOSE OF GRANTS.

(a) REQUIRED USES OF FUNDS.—The Secretary may not make payments under section 2401(a) unless the State involved agrees that the State will—

(1) provide for home and community-based health services for eligible individuals pursuant to written plans of care established by health care professionals for providing such services to such individuals;

(2) provide for the identification, location, and provision of outreach to eligible individuals;

(3) provide for coordinating the provision of services under this part with the provision of similar or related services by public and private entities; and

(4) give priority to the provision of outreach and home and community-based services to eligible individuals with low incomes.

(b) AUTHORITY FOR GRANTS AND CONTRACTS.—A State may make payment for services under subsection (a) through grants to public and nonprofit private entities and through contracts with public and private entities. In providing such financial assistance, a State shall give priority to public and nonprofit private entities that have demonstrated experience in delivering home and community-based health services to individuals infected with the etiologic agent for acquired immune deficiency syndrome.

SEC. 2403. [300dd-2] REQUIREMENT OF SUBMISSION OF DESCRIPTION OF INTENDED USES OF GRANT.

The Secretary may not make payments under section 2401(a) to a State for a fiscal year unless—

(1) the State submits to the Secretary a description of the purposes for which the State intends to expend such payments for the fiscal year;

(2) such description provides information relating to the services and activities to be provided, including a description of the manner in which such services and activities will be coordinated with any similar services and activities of public and private entities; and

(3) such description includes information relating to (A) the process for determining which eligible individuals are medically dependent or chronically dependent and (B) the process for establishing written plans of care for the provision of home and community-based health services under this part.

SEC. 2404. [300dd-3] RESTRICTIONS ON USE OF GRANT.

(a) IN GENERAL.—The Secretary may not make payments under section 2401(a) for a fiscal year to a State unless the State agrees that the payments will not be expended—

(1) to provide for items or services described in section 2401(d)(3);

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve real property (other than minor remodeling of existing improvements to real property) or to purchase major medical equipment; or

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds.

(b) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make payments under section 2401(a) for a fiscal year unless the State involved agrees that the State will not expend more than 5 percent of the payments made to the State under such section for administrative expenses with respect to carrying out the purpose of this part.

(c) LIMITATION ON TOTAL PAYMENTS.—

(1) Before March 1, 1989, for fiscal year 1989 and before September 1, 1989, for fiscal year 1990, the Secretary shall determine and publish the national average monthly payments, for extended care services under part A of title XVIII of the Social Security Act, for each resident of a skilled nursing facility the Secretary estimates will be paid in the fiscal year.

(2) The Secretary may not make payments under section 2401(a) for a fiscal year to a State to the extent that the average monthly payments for eligible individuals provided home and community-based health services under this part in the State exceeds 65 percent of the national average monthly payments determined and published for the fiscal year under paragraph (1).

SEC. 2405. [300dd-4] REQUIREMENT OF REPORTS AND AUDITS BY STATES.

(a) REPORTS.—

(1) The Secretary may not make payments under section 2401(a) for a fiscal year unless the State involved agrees to prepare and submit to the Secretary, by not later than January 1 following the fiscal year, an annual report in such form and containing such information as the Secretary determines (after consultation with the States and the Comptroller General of the United States) to be necessary for—

(A) securing a record and a description of the purposes for which payments received by the State pursuant to section 2401(a) were expended and of the recipients of such payments;

(B) determining whether the payments were expended in accordance with the purpose of this part; and

(C) determining the percentage of payments received pursuant to section 2401(a) that were expended by the State for administrative expenses during the fiscal year involved.

(2) Each report by a State under paragraph (1) for a fiscal year also shall include—

(A) information on the number and type of eligible individuals provided home and community-based health services by the State under this part for the fiscal year;

(B) information on the types of home and community-based health services so provided;

(C) information on the average monthly costs of such services and a comparison of such costs with costs of providing services in hospitals, nursing facilities, and similar institutions; and

(D) such other information as the Secretary may require to provide for an evaluation of the program under this part and its cost-effectiveness.

(b) AUDITS.—

(1) The Secretary may not make payments under section 2401(a) for a fiscal year unless the State involved agrees to establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursement of, and accounting for, amounts received by the State under such section.

(2) The Secretary may not make payments under section 2401(a) for a fiscal year unless the State involved agrees that—

(A) the State will provide for—

(i) a financial and compliance audit of such payments; or

(ii) a single financial and compliance audit of each entity administering such payments;

(B) the audit will be performed biennially and will cover expenditures in each fiscal year; and

(C) the audit will be conducted in accordance with standards established by the Comptroller General of the United States for the audit of governmental organizations, programs, activities, and functions.

(3) The Secretary may not make payments under section 2401(a) for a fiscal year unless the State involved agrees that, not later than 30 days after the completion of an audit under

paragraph (2), the State will provide a copy of the audit report to the State legislature.

(4) For purposes of paragraph (2), the term "financial and compliance audit" means an audit to determine whether the financial statements of an audited entity present fairly the financial position, and the results of financial operations, of the entity in accordance with generally accepted accounting principles, and whether the entity has complied with laws and regulations that may have a material effect upon the financial statements.

(c) **AVAILABILITY TO PUBLIC.**—The Secretary may not make payments under section 2401(a) unless the State involved agrees to make copies of the reports and audits described in this section available for public inspection.

(d) **EVALUATIONS BY COMPTROLLER GENERAL.**—The Comptroller General of the United States shall, from time to time, evaluate the expenditures by the States of payments under section 2401(a) in order to assure that expenditures are consistent with the provisions of this part.

SEC. 2406. [300dd-5] ADDITIONAL REQUIRED AGREEMENTS.

(a)¹ **IN GENERAL.**—The Secretary may not make payments under section 2401(a) for a fiscal year unless the State involved agrees that—

(1) the legislature of the State will conduct public hearings on the proposed use and distribution of the payments to be received from the allotments for each such fiscal year;

(2)(A) the State will, to the maximum extent practicable, ensure that services provided to an individual pursuant to the program involved will be provided without regard to the ability of the individual to pay for such services and without regard to the current or past health condition of the individual;

(B) if any charges are imposed for the provision of home and community-based health services for which assistance is provided under this part, such charges (i) will be pursuant to a public schedule of charges, (ii) will not be imposed on any eligible individual with an income that does not exceed 100 percent of the official poverty line, and (iii) for an eligible individual with an income that exceeds 100 percent of the official poverty line, will be adjusted to reflect the income of the individual;

(3) the State will provide for periodic independent peer review to assess the quality and appropriateness of home and community-based health services provided by entities that receive funds from the State pursuant to section 2401(a);

(4) the State will permit and cooperate with Federal investigations undertaken under section 2409(e);

(5) the State will maintain State expenditures for home and community-based health services for individuals infected with the etiologic agent for acquired immune deficiency syndrome at a level equal to not less than the average level of such expenditures maintained by the State for the 2-year pe-

¹ So in original. This section does not contain a subsection (b).

riod preceding the fiscal year for which the State is applying to receive payments; and

(6) the State will not make payments from allotments made under section 2401(a) for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service (i) under any State compensation program, under an insurance policy, under any Federal or State health benefits program, or (ii) by an entity that provides health services on a prepaid basis.

SEC. 2407. [300dd-6] REQUIREMENT OF SUBMISSION OF APPLICATION CONTAINING CERTAIN AGREEMENTS AND ASSURANCES.

The Secretary may not make payments under section 2401(a) to a State for a fiscal year unless—

(1) the State submits to the Secretary an application for the payments containing agreements in accordance with sections 2401 through 2406;

(2) the agreements are made through certification from the chief executive officer of the State;

(3) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary;

(4) the application contains the description of intended expenditures required in section 2403; and

(5) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

SEC. 2408. [300dd-7] DETERMINATION OF AMOUNT OF ALLOTMENTS FOR STATES.

(a) **MINIMUM ALLOTMENT.**—Subject to the extent of amounts made available in appropriations Acts, the amount of an allotment under section 2401(a) for—

(1) each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, for a fiscal year shall be the greater of—

(A) \$100,000, and

(B) an amount determined under subsection (b); and

(2) each territory of the United States (as defined in section 2413(5)) shall be \$25,000.

(b) **DETERMINATION UNDER FORMULA.**—

(1) The amount referred to in subsection (a)(1)(B) for a State is the product of—

(A) an amount equal to the amount appropriated pursuant to section 2414(a) for the fiscal year involved; and

(B) the ratio of the distribution factor for the State to the sum of the distribution factors for all the States.

(2) In paragraph (1)(B), the term “distribution factor” means, for a State, the product of—

(A) the number in the State of additional cases of acquired immune deficiency syndrome, as indicated by the number of such cases reported to and confirmed by the Secretary for the most recent fiscal year for which such data are available, and

(B) the ratio (based on the most recent available data) of (i) the average per capita income of individuals in the United States to (ii) the average per capita income of individuals in the State;

except that the distribution factors for all the States and territories shall be proportionally reduced to the extent necessary to assure that the total of the allotments under subsection (a) for all the States and territories for each fiscal year does not exceed the amount appropriated pursuant to section 2414(a) for the fiscal year.

(c) INDIAN TRIBES.—

(1) Upon the request of the governing body of an Indian tribe or tribal organization within a State to the Secretary, the Secretary shall—

(A) reserve from the amount that otherwise would be allotted for the fiscal year to the State under subsection (a) an amount determined in accordance with paragraph (2); and

(B) grant the amount reserved under subparagraph (A) to the Indian tribe or tribal organization serving eligible individuals who are members of the Indian tribe or tribal organization.

(2) The amount reserved under paragraph (1)(A) shall be an amount equal to the product of—

(A) the amount that otherwise would be allotted to the State under subsection (a) for the fiscal year; and

(B) the Secretary's estimate of the proportion of the number of additional cases described in subsection (b)(2)(A) that are attributable to members of the Indian tribe or tribal organization.

(3) The Secretary may not make a grant under paragraph (1)(B) to an Indian tribe or tribal organization unless the Indian tribe or tribal organization submits to the Secretary an application meeting the requirements of such an application under section 2407.

(d) DISPOSITION OF CERTAIN FUNDS APPROPRIATED FOR ALLOTMENTS.—

(1) Amounts described in paragraph (2) shall, in accordance with paragraph (3), be allotted by the Secretary to States receiving payments under section 2401(a) for the fiscal year (other than any State referred to in paragraph (2)(B)).

(2) The amounts referred to in paragraph (1) are any amounts that are not paid to States or territories under section 2401(a) as a result of—

(A) the failure of any State or territory to submit an application under section 2407 within a reasonable time period established by the Secretary; or

(B) any State or territory informing the Secretary that the State or territory does not intend to expend the full amount of the allotment made to the State or territory.

(3) The amount of an allotment under paragraph (1) for a State for a fiscal year shall be an amount equal to the product of—

(A) an amount equal to the amount described in paragraph (2) for the fiscal year involved; and

(B) the ratio determined under subsection (b)(1)(B) for the State.

SEC. 2409. [300dd-8] FAILURE TO COMPLY WITH AGREEMENTS.

(a) REPAYMENT OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), require a State to repay any payments received by the State under section 2401(a) that the Secretary determines were not expended by the State in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 2407.

(2) If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against the amount of any payment due to be paid to the State under section 2401(a).

(b) WITHHOLDING OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), withhold payments due under section 2401(a) if the Secretary determines that the State involved is not expending amounts received under such section in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 2407.

(2) The Secretary shall cease withholding payments from a State under paragraph (1) if the Secretary determines that there are reasonable assurances that the State will expend amounts received under section 2401(a) in accordance with the agreements referred to in such paragraph.

(c) OPPORTUNITY FOR HEARING.—Before requiring repayment of payments under subsection (a)(1), or withholding payments under subsection (b)(1), the Secretary shall provide to the State an opportunity for a hearing conducted within the State.

(d) TECHNICAL VIOLATIONS.—The Secretary may not require repayment under subsection (a)(1), or withhold payments under subsection (b)(1), for a technical violation, as determined by the Secretary, of any agreement required to be contained in the application submitted by the State pursuant to section 2407.

(e) INVESTIGATIONS.—

(1) The Secretary shall conduct in several States in each fiscal year investigations of the expenditure of payments received by the States under section 2401(a) in order to evaluate compliance with the agreements required to be contained in the applications submitted to the Secretary pursuant to section 2407.

(2) Each State, and each entity receiving funds from payments made to a State under section 2401(a), shall make appropriate books, documents, papers, and records available to the Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefor.

(3)(A) In conducting any investigation in a State, the Secretary and the Comptroller General of the United States may not make a request for any information not readily available to the State, or to an entity receiving funds from payments made to the State under section 2401(a), or make an unreasonable request for information to be compiled, collected, or transmitted in any form not readily available.

(B) Subparagraph (A) shall not apply to the collection, compilation, or transmittal of data in the course of a judicial proceeding.

SEC. 2410. [300dd-9] PROHIBITION AGAINST CERTAIN FALSE STATEMENTS.

(a) IN GENERAL.—A person may not knowingly make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which amounts may be paid by a State from payments received by the State under section 2401(a).

(b) CRIMINAL PENALTY FOR VIOLATION OF PROHIBITION.—Any person who violates a prohibition established in subsection (a) may for each violation be fined in accordance with title 18, United States Code, or imprisoned for not more than 5 years, or both.

SEC. 2411. [300dd-10] TECHNICAL ASSISTANCE AND PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) TECHNICAL ASSISTANCE.—Upon the request of a State receiving payments under section 2401(a), the Secretary may, without charge to the State, provide to the State (or to any public or private entity designated by the State) technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to this part. The Secretary may provide such technical assistance directly, through contract, or through grants.

(b) PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) Upon the request of a State receiving payments under section 2401(a), the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out this part and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under section 2401(a) to the State by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 2412. [300dd-11] REPORT BY SECRETARY.

Not later than March 1, 1990, the Secretary shall report to the Congress on the activities of the States under this part. Such report shall include a recommendation as to whether or not the program under this part should be extended beyond fiscal year 1990

and may include any recommendations of the Secretary for appropriate administrative and legislative initiatives.

SEC. 2413. [300dd-12] DEFINITIONS.

For purposes of this part:

(1) The terms "Indian tribe" and "tribal organization" have the same meaning given such terms in sections 4(b) and 4(c) of the Indian Self-Determination and Education Assistance Act.

(2) The term "infected with the etiologic agent for acquired immune deficiency syndrome" includes any condition arising from infection with such etiologic agent.

(3)(A) An individual is considered to have low income if the individual's income does not exceed 200 percent of the official poverty line.

(B) The term "official poverty line" refers, with respect to an individual, to the official poverty line defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981, applicable to a family of the size involved.

(4)(A) The term "State" means, except as provided in subparagraph (B), each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, and each territory of the United States.

(B) For purposes of subsections (b) and (d) of section 2408, the term "State" means each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico.

(5) The term "territory of the United States" means each of the following: the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

SEC. 2414. [300dd-13] FUNDING.

(a) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of making allotments under section 2401(a), there are authorized to be appropriated \$100,000,000 for each of the fiscal years 1989 and 1990.

(b) **AVAILABILITY TO STATES.**—Any amounts paid to a State or territory under section 2401(a) shall remain available to the State or territory until the expiration of the 1-year period beginning on the date on which the State or territory receives such amounts.

SEC. 2415. [300dd-14] SUNSET.

Effective with respect to appropriations made for any period after fiscal year 1990, this part is repealed.

PART B—SUBACUTE CARE

SEC. 2421. [300dd-21] DEMONSTRATION PROJECTS.

(a) As used in this section:

(1) The term "individuals infected with the etiologic agent for acquired immune deficiency syndrome" means individuals who have a disease, or are recovering from a disease, attributable to the infection of such individuals with such etiologic agent, and as a result of the effects of such disease, are in need of subacute-care services.

(2) The term "subacute care" means medical and health care services that are required for individuals recovering from acute care episodes that are less intensive than the level of care provided in acute-care hospitals, and includes skilled nursing care, hospice care, and other types of health services provided in other long-term-care facilities.

(b) The Secretary shall conduct three demonstration projects to determine the effectiveness and cost of providing the subacute-care services described in subsection (b) to individuals infected with the etiologic agent for acquired immune deficiency syndrome, and the impact of such services on the health status of such individuals.

(c)(1) The services provided under each demonstration project shall be designed to meet the specific needs of individuals infected with the etiologic agent for acquired immune deficiency syndrome, and shall include—

(A) the care and treatment of such individuals by providing—

(i) subacute care;

(ii) emergency medical care and specialized diagnostic and therapeutic services as needed and where appropriate, either directly or through affiliation with a hospital that has experience in treating individuals with acquired immune deficiency syndrome; and

(iii) case management services to ensure, through existing services and programs whenever possible, appropriate discharge planning for such individuals; and

(B) technical assistance, to other facilities in the region served by such facility, that is directed toward education and training of physicians, nurses, and other health-care professionals in the subacute care and treatment of individuals infected with the etiologic agent for acquired immune deficiency syndrome.

(2) Services provided under each demonstration project may also include—

(A) hospice services;

(B) outpatient care; and

(C) outreach activities in the surrounding community to hospitals and other health-care facilities that serve individuals infected with the etiologic agent for acquired immune deficiency syndrome.

(d) The demonstration projects shall be conducted—

(1) during a 4-year period beginning not later than 9 months after the date of enactment of this section;¹ and

(2) at sites that—

(A) are geographically diverse and located in areas that are appropriate for the provision of the required and authorized services; and

(B) have the highest incidence of cases of acquired immune deficiency syndrome and the greatest need for subacute-care services.

(e) The Secretary shall evaluate the operations of the demonstration projects and shall submit to the Committee on Energy

¹ Enacted on November 4, 1988.

and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate—

(1) not later than 18 months after the beginning of the first project, a preliminary report that contains—

(A) a description of the sites at which the projects are being conducted and of the services being provided in each project; and

(B) a preliminary evaluation of the experience of the projects in the first 12 months of operation; and

(2) not later than 6 months after the completion of the last project, a final report that contains—

(A) an assessment of the costs of subacute care for individuals infected with the etiologic agent for acquired immune deficiency syndrome, including a breakdown of all other sources of funding for the care provided to cover subacute care; and

(B) recommendations for appropriate legislative changes.

(f) Each demonstration project shall provide for other research to be carried out at the site of such demonstration project including—

(1) clinical research on acquired immune deficiency syndrome, concentrating on research on the neurological manifestations resulting from infection with the etiologic agent for such syndrome; and

(2) the study of the psychological and mental health issues related to such syndrome.

(g)(1) To carry out this section, there are authorized to be appropriated \$10,000,000 for fiscal year 1989 and such sums as are necessary for each of the fiscal years 1990 through 1992.

(2) Amounts appropriated pursuant to paragraph (1) shall remain available until September 10, 1992.

(h) The Secretary shall enter into an agreement with the Administrator of the Veterans' Administration to ensure that appropriate provision will be made for the furnishing, through demonstration projects, of services to eligible veterans, under contract with the Veterans' Administration pursuant to section 620 of title 38, United States Code.

PART C—OTHER HEALTH SERVICES

SEC. 2431. [300dd-31] GRANTS FOR ANONYMOUS TESTING.

The Secretary may make grants to the States for the purpose of providing opportunities for individuals—

(1) to undergo counseling and testing with respect to the etiologic agent for acquired immune deficiency syndrome without being required to provide any information relating to the identity of the individuals; and

(2) to undergo such counseling and testing through the use of a pseudonym.

SEC. 2432. [300dd-32] REQUIREMENT OF PROVISION OF CERTAIN COUNSELING SERVICES.

(a) COUNSELING BEFORE TESTING.—The Secretary may not make a grant under section 2431 to a State unless the State agrees

that, before testing an individual pursuant to such section, the State will provide to the individual appropriate counseling with respect to acquired immune deficiency syndrome (based on the most recent scientific data relating to such syndrome), including—

(1) measures for the prevention of exposure to, and the transmission of, the etiologic agent for such syndrome;

(2) the accuracy and reliability of the results of such testing;

(3) the significance of the results of such testing, including the potential for developing acquired immune deficiency syndrome; and

(4) encouraging individuals, as appropriate, to undergo testing for such etiologic agent and providing information on the benefits of such testing.

(b) COUNSELING OF INDIVIDUALS WITH NEGATIVE TEST RESULTS.—The Secretary may not make a grant under section 2431 to a State unless the State agrees that, if the results of testing conducted pursuant to such section indicate that an individual is not infected with the etiologic agent for acquired immune deficiency syndrome, the State will review for the individual the information provided pursuant to subsection (a) with respect to such syndrome, including—

(1) the information described in paragraphs (1) through (3) of such subsection; and

(2) the appropriateness of further counseling, testing, and education of the individual with respect to acquired immune deficiency syndrome.

(c) COUNSELING OF INDIVIDUALS WITH POSITIVE TEST RESULTS.—The Secretary may not make a grant under section 2431 to a State unless the State agrees that, if the results of testing conducted pursuant to such section indicate that an individual is infected with the etiologic agent for acquired immune deficiency syndrome, the State will provide to the individual appropriate counseling with respect to such syndrome, including—

(1) reviewing the information described in paragraphs (1) through (3) of subsection (a);

(2) reviewing the appropriateness of further counseling, testing, and education of the individual with respect to acquired immune deficiency syndrome;

(3) the importance of not exposing others to the etiologic agent for acquired immune deficiency syndrome;

(4) the availability in the geographic area of any appropriate services with respect to health care, including mental health care and social and support services;

(5) the benefits of locating and counseling any individual by whom the infected individual may have been exposed to the etiologic agent for acquired immune deficiency syndrome and any individual whom the infected individual may have exposed to such etiologic agent; and

(6) the availability, if any, of the services of public health authorities with respect to locating and counseling any individual described in paragraph (5).

(d) RULE OF CONSTRUCTION WITH RESPECT TO COUNSELING WITHOUT TESTING.—Agreements entered into pursuant to sub-

sections (a) through (c) may not be construed to prohibit any grantee under section 2431 from expending the grant for the purpose of providing counseling services described in such subsections to an individual who will not undergo testing described in such section as a result of the grantee or the individual determining that such testing of the individual is not appropriate.

(e) USE OF FUNDS.—

(1) The purpose of this subpart¹ is to provide for counseling and testing services to prevent and reduce exposure to, and transmission of, the etiologic agent for acquired immune deficiency syndrome.

(2) All individuals receiving counseling pursuant to this subpart¹ are to be counseled about the harmful effects of promiscuous sexual activity and intravenous substance abuse, and the benefits of abstaining from such activities.

(3) None of the fund appropriated to carry out this subpart¹ may be used to provide counseling that is designed to promote or encourage, directly, homosexual or heterosexual sexual activity or intravenous drug abuse.

(4) Paragraph (3) may not be construed to prohibit a counselor who has already performed the counseling of an individual required by paragraph (2), to provide accurate information about means to reduce an individual's risk of exposure to, or the transmission of, the etiologic agent for acquired immune deficiency syndrome, provided that any informational materials used are not obscene.

SEC. 2433. [300dd-33] FUNDING.

For the purpose of grants under section 2431, there are authorized to be appropriated \$100,000,000 for each of the fiscal years 1989 and 1990.

¹Probably should be "part". See section 118(b)(1)(B) of Public Law 102-321 (106 Stat. 348).

TITLE XXV—PREVENTION OF ACQUIRED IMMUNE DEFICIENCY SYNDROME¹

SEC. 2500. [300ee] USE OF FUNDS.

(a) IN GENERAL.—The purpose of this title is to provide for the establishment of education and information programs to prevent and reduce exposure to, and the transmission of, the etiologic agent for acquired immune deficiency syndrome.

(b) CONTENTS OF PROGRAMS.—All programs of education and information receiving funds under this title shall include information about the harmful effects of promiscuous sexual activity and intravenous substance abuse, and the benefits of abstaining from such activities.

(c) LIMITATION.—None of the funds appropriated to carry out this title may be used to provide education or information designed to promote or encourage, directly, homosexual or heterosexual sexual activity or intravenous substance abuse.

(d) CONSTRUCTION.—Subsection (c) may not be construed to restrict the ability of an education program that includes the information required in subsection (b) to provide accurate information about various means to reduce an individual's risk of exposure to, or the transmission of, the etiologic agent for acquired immune deficiency syndrome, provided that any informational materials used are not obscene.

PART A—FORMULA GRANTS TO STATES

SEC. 2501. [300ee-11] ESTABLISHMENT OF PROGRAM.

(a) ALLOTMENTS FOR STATES.—For the purpose described in subsection (b), the Secretary shall for each of the fiscal years 1989 through 1991 make an allotment for each State in an amount determined in accordance with section 2507. The Secretary shall make payments each such fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 2503.

(b) PURPOSE OF GRANTS.—The Secretary may not make payments under subsection (a) for a fiscal year unless the State involved agrees to expend the payments only for the purpose of carrying out, in accordance with section 2502, public information activities with respect to acquired immune deficiency syndrome.

SEC. 2502. [300ee-12] PROVISIONS WITH RESPECT TO CARRYING OUT PURPOSE OF GRANTS.

A State may expend payments received under section 2501(a)—

¹ See footnote 1 on page 794.

(1) to develop, establish, and conduct public information activities relating to the prevention and diagnosis of acquired immune deficiency syndrome for those populations or communities in the State in which there are a significant number of individuals at risk of infection with the etiologic agent for such syndrome;

(2) to develop, establish, and conduct such public information activities for the general public relating to the prevention and diagnosis of such syndrome;

(3) to develop, establish, and conduct activities to reduce risks relating to such syndrome, including research into the prevention of such syndrome;

(4) to conduct demonstration projects for the prevention of such syndrome;

(5) to provide technical assistance to public entities, to nonprofit private entities concerned with such syndrome, to schools, and to employers, for the purpose of developing information programs relating to such syndrome;

(6) with respect to education and training programs for the prevention of such syndrome, to conduct such programs for health professionals (including allied health professionals), public safety workers (including emergency response employees), teachers, school administrators, and other appropriate education personnel;

(7) to conduct appropriate programs for educating school-aged children with respect to such syndrome, after consulting with local school boards;

(8) to make available to physicians and dentists in the State information with respect to acquired immune deficiency syndrome, including measures for the prevention of exposure to, and the transmission of, the etiologic agent for such syndrome (which information is updated not less than annually with the most recently available scientific data¹ relating to such syndrome);

(9) to carry out the initial implementation of recommendations contained in the guidelines and the model curriculum developed under section 253 of the AIDS Amendments of 1988; and

(10) to make grants to public entities, and to nonprofit private entities concerned with acquired immune deficiency syndrome, for the purpose of the development, establishment, and expansion of programs for education directed toward individuals at increased risk of infection with the etiologic agent for such syndrome and activities to reduce the risks of exposure to such etiologic agent, with preference to programs directed toward populations in which there is significant evidence of such infection.

SEC. 2503. [300ee-13] REQUIREMENT OF SUBMISSION OF APPLICATION CONTAINING CERTAIN AGREEMENTS AND ASSURANCES.

(a) IN GENERAL.—The Secretary may not make payments under section 2501(a) for a fiscal year unless—

¹ So in original. Probably should be "data".

(1) the State involved submits to the Secretary a description of the purposes for which the State intends to expend the payments for the fiscal year;

(2) the description identifies the populations, areas, and localities in the State with a need for the services for which amounts may be provided by the State under this part;

(3) the description provides information relating to the programs and activities to be supported and services to be provided, including a description of the manner in which such programs and activities will be coordinated with any similar programs and activities of public and private entities;

(4) the State submits to the Secretary an application for the payments containing agreements in accordance with this part;

(5) the agreements are made through certification from the chief executive officer of the State;

(6) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary; and

(7) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

(b) **OPPORTUNITY FOR PUBLIC COMMENT.**—The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees that, in developing and carrying out the description required in subsection (a), the State will provide public notice with respect to the description (including any revisions) and will facilitate comments from interested persons.

SEC. 2504. [300ee-14] RESTRICTIONS ON USE OF GRANT.

(a) **IN GENERAL.**—The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees that the payments will not be expended—

(1) to provide inpatient services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve real property (other than minor remodeling of existing improvements to real property) or to purchase major medical equipment; or

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds.

(b) **LIMITATION ON ADMINISTRATIVE EXPENSES.**—The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees that the State will not expend more than 5 percent of the payments for administrative expenses with respect to carrying out the purpose described in section 2501(b).

SEC. 2505. [300ee-15] REQUIREMENT OF REPORTS AND AUDITS BY STATES.

(a) **REPORTS.**—The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees to prepare and submit to the Secretary an annual report in such form and containing such information as the Secretary determines to be necessary for—

(1) securing a record and a description of the purposes for which payments received by the State pursuant to such section were expended and of the recipients of such payments;

(2) determining whether the payments were expended in accordance with the needs within the State required to be identified pursuant to section 2503(a)(2);

(3) determining whether the payments were expended in accordance with the purpose described in section 2501(b); and

(4) determining the percentage of payments received pursuant to such section that were expended by the State for administrative expenses during the preceding fiscal year.

(b) AUDITS.—

(1) The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees to establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State under such section.

(2) The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees that—

(A) the State will provide for—

(i) a financial and compliance audit of such payments; or

(ii) a single financial and compliance audit of each entity administering such payments;

(B) the audit will be performed biennially and will cover expenditures in each fiscal year; and

(C) the audit will be conducted in accordance with standards established by the Comptroller General of the United States for the audit of governmental organizations, programs, activities, and functions.

(3) The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees that, not later than 30 days after the completion of an audit under paragraph (2), the State will provide a copy of the audit report to the State legislature.

(4) For purposes of paragraph (2), the term “financial and compliance audit” means an audit to determine whether the financial statements of an audited entity present fairly the financial position, and the results of financial operations, of the entity in accordance with generally accepted accounting principles, and whether the entity has complied with laws and regulations that may have a material effect upon the financial statements.

(c) AVAILABILITY TO PUBLIC.—The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees to make copies of the reports and audits described in this section available for public inspection.

(d) EVALUATIONS BY COMPTROLLER GENERAL.—The Comptroller General of the United States shall, from time to time, evaluate the expenditures by States of payments received under section 2501(a) in order to ensure that expenditures are consistent with the provisions of this part.

SEC. 2506. [300ee-16] ADDITIONAL REQUIRED AGREEMENTS.

(a) IN GENERAL.—The Secretary may not, except as provided in subsection (b), make payments under section 2501(a) for a fiscal year unless the State involved agrees that—

(1) all programs conducted or supported by the State with such payments will establish objectives for the program and will determine the extent to which the objectives are met;

(2) information provided under this part will be scientifically accurate and factually correct;

(3) in carrying out section 2501(b), the State will give priority to programs described in section 2502(10) for individuals described in such section;

(4) with respect to a State in which there is a substantial number of individuals who are intravenous substance abusers, the State will place priority on activities under this part directed at such substance abusers;

(5) with respect to a State in which there is a significant incidence of reported cases of acquired immune deficiency syndrome, the State will—

(A) for the purpose described in subsection (b) of section 2501, expend not less than 50 percent of payments received under subsection (a) of such section for a fiscal year—

(i) to make grants to public entities, to migrant health centers (as defined in section 329(a)), to community health centers (as defined in section 330(a)), and to nonprofit private entities concerned with acquired immune deficiency syndrome; or

(ii) to enter into contracts with public and private entities; and

(B) of the amounts reserved for a fiscal year by the State for expenditures required in subparagraph (A), expend not less than 50 percent to carry out section 2502(10) through grants to nonprofit private entities, including minority entities, concerned with acquired immune deficiency syndrome located in and representative of communities and subpopulations reflecting the local incidence of such syndrome;

(6) with respect to programs carried out pursuant to section 2502(10), the State will ensure that any applicant for a grant under such section agrees—

(A) that any educational or informational materials developed with a grant pursuant to such section will contain material, and be presented in a manner, that is specifically directed toward the group for which such materials are intended;

(B) to provide a description of the manner in which the applicant has planned the program in consultation with, and of the manner in which such applicant will consult during the conduct of the program with—

(i) appropriate local officials and community groups for the area to be served by the program;

(ii) organizations comprised of, and representing, the specific population to which the education or prevention effort is to be directed; and

(iii) individuals having expertise in health education and in the needs of the population to be served;

(C) to provide information demonstrating that the applicant has continuing relationships, or will establish continuing relationships, with a portion of the population in the service area that is at risk of infection with the etiologic agent for acquired immune deficiency syndrome and with public and private entities in such area that provide health or other support services to individuals with such infection;

(D) to provide a description of—

(i) the objectives established by the applicant for the conduct of the program; and

(ii) the methods the applicant will use to evaluate the activities conducted under the program to determine if such objectives are met; and

(E) such other information as the Secretary may prescribe;

(7) with respect to programs carried out pursuant to section 2502(10), the State will give preference to any applicant for a grant pursuant to such section that is located in, has a history of service in, and will serve under the program, any geographic area in which—

(A) there is a significant incidence of acquired immune deficiency syndrome;

(B) there has been a significant increase in the incidence of such syndrome; or

(C) there is a significant risk of becoming infected with the etiologic agent for such syndrome;

(8) the State will establish reasonable criteria to evaluate the effective performance of entities that receive funds from payments made to the State under section 2501(a) and will establish procedures for procedural and substantive independent State review of the failure by the State to provide funds for any such entity;

(9) the State will permit and cooperate with Federal investigations undertaken in accordance with section 2508(e);

(10) the State will maintain State expenditures for services provided pursuant to section 2501 at a level equal to not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying to receive payments.

(b) DEFINITION.—For purposes of subsection (a)(5), the term “significant percentage” means at least a percentage of 1 percent of the number of reported cases of acquired immune deficiency syndrome in the United States.

SEC. 2507. [300ee-17] DETERMINATION OF AMOUNT OF ALLOTMENTS FOR STATES.

(a) MINIMUM ALLOTMENT.—Subject to the extent of amounts made available in appropriation Acts, the allotment for a State under section 2501(a) for a fiscal year shall be the greater of—

- (1) the applicable amount specified in subsection (b); or
- (2) the amount determined in accordance with subsection

(c).

(b) DETERMINATION OF MINIMUM ALLOTMENT.—

(1) If the total amount appropriated under section 2514(a) for a fiscal year exceeds \$100,000,000, the amount referred to in subsection (a)(1) shall be \$300,000 for the fiscal year.

(2) If the total amount appropriated under section 2514(a) for a fiscal year equals or exceeds \$50,000,000, but is less than \$100,000,000, the amount referred to in subsection (a)(1) shall be \$200,000 for the fiscal year.

(3) If the total amount appropriated under section 2514(a) for a fiscal year is less than \$50,000,000, the amount referred to in subsection (a)(1) shall be \$100,000 for the fiscal year.

(c) DETERMINATION UNDER FORMULA.—

(1) The amount referred to in subsection (a)(2) is the sum of—

(A) the amount determined under paragraph (2); and

(B) the amount determined under paragraph (3).

(2) The amount referred to in paragraph (1)(A) is the product of—

(A) an amount equal to 50 percent of the amounts appropriated pursuant to section 2514(a); and

(B) a percentage equal to the quotient of—

(i) the population of the State involved; divided by

(ii) the population of the United States.

(3) The amount referred to in paragraph (1)(B) is the product of—

(A) an amount equal to 50 percent of the amounts appropriated pursuant to section 2514(a); and

(B) a percentage equal to the quotient of—

(i) the number of additional cases of acquired immune deficiency syndrome reported to and confirmed by the Secretary for the State involved for the most recent fiscal year for which such data is available; divided by

(ii) the number of additional cases of such syndrome reported to and confirmed by the Secretary for the United States for such fiscal year.

(d) DISPOSITION OF CERTAIN FUNDS APPROPRIATED FOR ALLOTMENTS.—

(1) Amounts described in paragraph (2) shall be allotted by the Secretary to States receiving payments under section 2501(a) for the fiscal year (other than any State referred to in paragraph (2)(C)). Such amounts shall be allotted according to a formula established by the Secretary. The formula shall be equivalent to the formula described in this section under which the allotment under section 2501(a) for the State for the fiscal year involved was determined.

(2) The amounts referred to in paragraph (1) are any amounts that are not paid to States under section 2501(a) as a result of—

(A) the failure of any State to submit an application under section 2503;

(B) the failure, in the determination of the Secretary, of any State to prepare within a reasonable period of time such application in compliance with such section; or

(C) any State informing the Secretary that the State does not intend to expend the full amount of the allotment made to the State.

SEC. 2508. [300ee-18] FAILURE TO COMPLY WITH AGREEMENTS.

(a) REPAYMENT OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), require a State to repay any payments received by the State under section 2501(a) that the Secretary determines were not expended by the State in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 2503.

(2) If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against the amount of any payment due to be paid to the State under section 2501(a).

(b) WITHHOLDING OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), withhold payments due under section 2501(a) if the Secretary determines that the State involved is not expending amounts received under such section in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 2503.

(2) The Secretary shall cease withholding payments from a State under paragraph (1) if the Secretary determines that there are reasonable assurances that the State will expend amounts received under section 2501(a) in accordance with the agreements referred to in such paragraph.

(3) The Secretary may not withhold funds under paragraph (1) from a State for a minor failure to comply with the agreements referred to in such paragraph.

(c) OPPORTUNITY FOR HEARING.—Before requiring repayment of payments under subsection (a)(1), or withholding payments under subsection (b)(1), the Secretary shall provide to the State an opportunity for a hearing conducted within the State.

(d) PROMPT RESPONSE TO SERIOUS ALLEGATIONS.—The Secretary shall promptly respond to any complaint of a substantial or serious nature that a State has failed to expend amounts received under section 2501(a) in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 2503.

(e) INVESTIGATIONS.—

(1) The Secretary shall conduct in several States in each fiscal year investigations of the expenditure of payments received by the States under section 2501(a) in order to evaluate compliance with the agreements required to be contained in the applications submitted to the Secretary pursuant to section 2503.

(2) The Comptroller General of the United States may conduct investigations of the expenditure of funds received under

section 2501(a) by a State in order to ensure compliance with the agreements referred to in paragraph (1).

(3) Each State, and each entity receiving funds from payments made to a State under section 2501(a), shall make appropriate books, documents, papers, and records available to the Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefor.

(4)(A) In conducting any investigation in a State, the Secretary and the Comptroller General of the United States may not make a request for any information not readily available to the State, or to an entity receiving funds from payments made to the State under section 2501(a), or make an unreasonable request for information to be compiled, collected, or transmitted in any form not readily available.

(B) Subparagraph (A) shall not apply to the collection, compilation, or transmittal of data in the course of a judicial proceeding.

SEC. 2509. [300ee-19] PROHIBITION AGAINST CERTAIN FALSE STATEMENTS.

(a) IN GENERAL.—

(1) A person may not knowingly make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which amounts may be paid by a State from payments received by the State under section 2501(a).

(2) A person with knowledge of the occurrence of any event affecting the right of the person to receive any amounts from payments made to the State under section 2501(a) may not conceal or fail to disclose any such event with the intent of fraudulently securing such amounts.

(b) CRIMINAL PENALTY FOR VIOLATION OF PROHIBITION.—Any person who violates a prohibition established in subsection (a) may for each violation be fined in accordance with title 18, United States Code, or imprisoned for not more than 5 years, or both.

SEC. 2510. [300ee-20] TECHNICAL ASSISTANCE AND PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) TECHNICAL ASSISTANCE.—The Secretary may provide training and technical assistance to States with respect to the planning, development, and operation of any program or service carried out pursuant to this part. The Secretary may provide such technical assistance directly or through grants or contracts.

(b) PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) Upon the request of a State receiving payments under this part, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out such part and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under section 2501(a) to the State by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 2511. [300ee-21] EVALUATIONS.

The Secretary shall, directly or through grants or contracts, evaluate the services provided and activities carried out with payments to States under this part.

SEC. 2512. [300ee-22] REPORT BY SECRETARY.

The Secretary shall annually prepare a report on the activities of the States carried out pursuant to this part. Such report may include any recommendations of the Secretary for appropriate administrative and legislative initiatives. The report shall be submitted to the Congress through inclusion in the comprehensive report required in section 2301(a).

SEC. 2513. [300ee-23] DEFINITION.

For purposes of this part, the term "infection with the etiologic agent for acquired immune deficiency syndrome" includes any condition arising from such etiologic agent.

SEC. 2514. [300ee-24] FUNDING.

(a) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of making allotments under section 2501(a), there are authorized to be appropriated \$165,000,000 for fiscal year 1989 and such sums as may be necessary for each of the fiscal years 1990 and 1991.

(b) **AVAILABILITY TO STATES.**—Any amounts paid to a State under section 2501(a) shall remain available to the State until the expiration of the 1-year period beginning on the date on which the State receives such amounts.

PART B—NATIONAL INFORMATION PROGRAMS

SEC. 2521. [300ee-31] AVAILABILITY OF INFORMATION TO GENERAL PUBLIC.

(a) **COMPREHENSIVE INFORMATION PLAN.**—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall annually prepare a comprehensive plan, including a budget, for a National Acquired Immune Deficiency Syndrome Information Program. The plan shall contain provisions to implement the provisions of this title. The Director shall submit such plan to the Secretary. The authority established in this subsection may not be construed to be the exclusive authority for the Director to carry out information activities with respect to acquired immune deficiency syndrome.

(b) **CLEARINGHOUSE.**—

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a clearinghouse to make information concerning acquired immune deficiency syndrome available to Federal agencies, States, public and private entities, and the general public.

(2) The clearinghouse may conduct or support programs—

(A) to develop and obtain educational materials, model curricula, and methods directed toward reducing the transmission of the etiologic agent for acquired immune deficiency syndrome;

(B) to provide instruction and support for individuals who provide instruction in methods and techniques of education relating to the prevention of acquired immune deficiency syndrome and instruction in the use of the materials and curricula described in subparagraph (A); and

(C) to conduct, or to provide for the conduct of, the materials, curricula, and methods described in paragraph (1) and the efficacy of such materials, curricula, and methods in preventing infection with the the¹ etiologic agent for acquired immune deficiency syndrome.

(c) **TOLL-FREE TELEPHONE COMMUNICATIONS.**—The Secretary shall provide for the establishment and maintenance of toll-free telephone communications to provide information to, and respond to queries from, the public concerning acquired immune deficiency syndrome. Such communications shall be available on a 24-hour basis.

SEC. 2522. [300ee-32] PUBLIC INFORMATION CAMPAIGNS.

(a) **IN GENERAL.**—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to public entities, and to nonprofit private entities concerned with acquired immune deficiency syndrome, and shall enter into contracts with public and private entities, for the development and delivery of public service announcements and paid advertising messages that warn individuals about activities which place them at risk of infection with the etiologic agent for such syndrome.

(b) **REQUIREMENT OF APPLICATION.**—The Secretary may not provide financial assistance under subsection (a) unless—

(1) an application for such assistance is submitted to the Secretary;

(2) with respect to carrying out the purpose for which the assistance is to be provided, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

SEC. 2523. [300ee-33] PROVISION OF INFORMATION TO UNDERSERVED POPULATIONS.

(a) **IN GENERAL.**—The Secretary may make grants to public entities, to migrant health centers (as defined in section 329(a)), to community health centers (as defined in section 330(a)), and to nonprofit private entities concerned with acquired immune deficiency syndrome, for the purpose of assisting grantees in providing services to populations of individuals that are underserved with respect to programs providing information on the prevention of exposure to, and the transmission of, the etiologic agent for acquired immune deficiency syndrome.

¹ So in original.

(b) **PREFERENCES IN MAKING GRANTS.**—In making grants under subsection (a), the Secretary shall give preference to any applicant for such a grant that has the ability to disseminate rapidly the information described in subsection (a) (including any national organization with such ability).

SEC. 2524. [300ee-34] AUTHORIZATION OF APPROPRIATIONS.

(a) **IN GENERAL.**—For the purpose of carrying out sections 2521 through 2523, there are authorized to be appropriated \$105,000,000 for fiscal year 1989 and such sums as may be necessary for each of the fiscal years 1990 and 1991.

(b) **ALLOCATIONS.**—

(1) Of the amounts appropriated pursuant to subsection (a), the Secretary shall make available \$45,000,000 to carry out section 2522 and \$30,000,000 to carry out this part through financial assistance to minority entities for the provision of services to minority populations.

(2) After consultation with the Director of the Office of Minority Health and with the Indian Health Service, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, not later than 90 days after the date of the enactment of the AIDS Amendments of 1988,¹ publish guidelines to provide procedures for applications for funding pursuant to paragraph (1) and for public comment.

¹ Enacted on November 4, 1988.

TITLE XXVI—HIV HEALTH CARE SERVICES PROGRAM ¹

PART A—EMERGENCY RELIEF FOR AREAS WITH SUBSTANTIAL NEED FOR SERVICES

SEC. 2601. [300ff-11] ESTABLISHMENT OF PROGRAM OF GRANTS.

(a) ELIGIBLE AREAS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall, subject to subsection (b), make grants in accordance with section 2603 for the purpose of assisting in the provision of the services specified in 2604² in any metropolitan area for which, as of June 30, 1990, in the case of grants for fiscal year 1991, and as of March 31 of the most recent fiscal year for which such data is available in the case of a grant for any subsequent fiscal year—

(1) there has been reported to and confirmed by the Director of the Centers for Disease Control and Prevention a cumulative total of more than 2,000 cases of acquired immune deficiency syndrome; or

(2) the per capita incidence of cumulative cases of such syndrome (computed on the basis of the most recently available data on the population of the area) is not less than 0.0025.

(b) REQUIREMENT REGARDING CONFIRMATION OF CASES.—The Secretary may not make a grant under subsection (a) for a metropolitan area unless, before making any payments under the grant, the cases of acquired immune deficiency syndrome reported for purposes of such subsection have been confirmed by the Secretary, acting through the Director of the Centers for Disease Control and Prevention.

SEC. 2602. [300ff-12] ADMINISTRATION AND PLANNING COUNCIL.

(a) ADMINISTRATION.—

(1) IN GENERAL.—Assistance made available under grants awarded under this part shall be directed to the chief elected official of the city or urban county that administers the public health agency that provides outpatient and ambulatory services to the greatest number of individuals with AIDS, as reported to and confirmed by the Centers for Disease Control and Prevention, in the eligible area that is awarded such a grant.

(2) REQUIREMENTS.—

¹This title was added by Public Law 101-381. Section 2 of that Public Law provides as follows: "It is the purpose of this Act to provide emergency assistance to localities that are disproportionately affected by the Human Immunodeficiency Virus epidemic and to make financial assistance available to States and other public or private nonprofit entities to provide for the development, organization, coordination and operation of more effective and cost efficient systems for the delivery of essential services to individuals and families with HIV disease."

²So in original. See Public Law 101-381. Probably should be "section 2604".

(A) IN GENERAL.—To receive assistance under section 2601(a), the chief elected official of the eligible area involved shall—

(i) establish, through intergovernmental agreements with the chief elected officials of the political subdivisions described in subparagraph (B), an administrative mechanism to allocate funds and services based on—

(I) the number of AIDS cases in such subdivisions;

(II) the severity of need for outpatient and ambulatory care services in such subdivisions; and

(III) the health and support services personnel needs of such subdivisions; and

(ii) establish an HIV health services planning council in accordance with subsection (b).

(B) LOCAL POLITICAL SUBDIVISION.—The political subdivisions referred to in subparagraph (A) are those political subdivisions in the eligible area—

(i) that provide HIV-related health services; and

(ii) for which the number of cases reported for purposes of section 2601(a) constitutes not less than 10 percent of the number of such cases reported for the eligible area.

(b) HIV HEALTH SERVICES PLANNING COUNCIL.—

(1) ESTABLISHMENT.—To be eligible for assistance under this part, the chief elected official described in subsection (a)(1) shall establish or designate an HIV health services planning council that shall include representatives of—

(A) health care providers;

(B) community-based and AIDS service organizations;

(C) social service providers;

(D) mental health care providers;

(E) local public health agencies;

(F) hospital planning agencies or health care planning agencies;

(G) affected communities, including individuals with HIV disease;

(H) non-elected community leaders;

(I) State government;

(J) grantees under subpart II of part C; and

(K) the lead agency of any Health Resources and Services Administration adult and pediatric HIV-related care demonstration project operating in the area to be served.

(2) METHOD OF PROVIDING FOR COUNCIL.—

(A) IN GENERAL.—In providing for a council for purposes of paragraph (1), a chief elected official receiving a grant under section 2601(a) may establish the council directly or designate an existing entity to serve as the council, subject to subparagraph (B).

(B) CONSIDERATION REGARDING DESIGNATION OF COUNCIL.—In making a determination of whether to establish or designate a council under subparagraph (A), a chief elected official receiving a grant under section 2601(a) shall give

priority to the designation of an existing entity that has demonstrated experience in planning for the HIV health care service needs within the eligible area and in the implementation of such plans in addressing those needs. Any existing entity so designated shall be expanded to include a broad representation of the full range of entities that provide such services within the geographic area to be served.

(3) DUTIES.—The planning council established or designated under paragraph (1) shall—

(A) establish priorities for the allocation of funds within the eligible area;

(B) develop a comprehensive plan for the organization and delivery of health services described in section 2604 that is compatible with any existing State or local plan regarding the provision of health services to individuals with HIV disease; and

(C) assess the efficiency of the administrative mechanism in rapidly allocating funds to the areas of greatest need within the eligible area.

SEC. 2603. [300ff-13] TYPE AND DISTRIBUTION OF GRANTS.

(a) GRANTS BASED ON RELATIVE NEED OF AREA.—

(1) IN GENERAL.—In carrying out section 2601(a), the Secretary shall make a grant for each eligible area for which an application under section 2605(a) has been approved. Each such grant shall be made in an amount determined in accordance with paragraph (3).

(2) EXPEDITED DISTRIBUTION.—Not later than—

(A) 90 days after an appropriation becomes available to carry out this part for fiscal year 1991; and

(B) 60 days after an appropriation becomes available to carry out this part for each of fiscal years 1992 through 1995;

the Secretary shall, except in the case of waivers granted under section 2605(c), disburse 50 percent of the amount appropriated under section 2608 for such fiscal year through grants to eligible areas under section 2601(a).

(3) AMOUNT OF GRANT.—

(A) IN GENERAL.—

(i) Subject to the extent of amounts made available in appropriations Acts, a grant made for purposes of this paragraph to an eligible area shall be made in an amount equal to the product of—

(I) an amount equal to the amount available for distribution under paragraph (2) for the fiscal year involved; and

(II) the percentage constituted by the ratio of the distribution factor for the eligible area to the sum of the respective distribution factors for all eligible areas.

(ii) For purposes of clause (i)(II), the term “distribution factor” means the sum of—

(I) an amount equal to the product of 3 and the amount determined under subparagraph (B) for the eligible area involved; and

(II) an amount equal to the product of the amount determined under subparagraph (B) for the eligible area and the amount determined under subparagraph (C) for the area.

(B) AMOUNT RELATING TO CUMULATIVE NUMBER OF CASES.—The amount determined in this subparagraph is an amount equal to the ratio of—

(i) an amount equal to the cumulative number of cases of acquired immune deficiency syndrome in the eligible area involved, as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control and Prevention by the applicable date specified in section 2601(a); to

(ii) an amount equal to the sum of the respective amounts determined under clause (i) for each eligible area for which an application for a grant for purposes of this paragraph has been approved.

(C) AMOUNT RELATING TO PER CAPITA INCIDENCE OF CASES.—The amount determined in this subparagraph is an amount equal to the ratio of—

(i) the per capita incidence of cumulative cases of acquired immune deficiency syndrome in the eligible area involved (computed on the basis of the most recently available data on the population of the area); to

(ii) the per capita incidence of cumulative such cases in all eligible areas for which applications for grants for purposes of this paragraph have been approved (computed on the basis of the most recently available data on the population of the areas).

(b) SUPPLEMENTAL GRANTS.—

(1) IN GENERAL.—Not later than 150 days after the date on which appropriations are made under section 2608 for a fiscal year, the Secretary shall disburse the remainder of amounts not disbursed under section 2603(a)(2) for such fiscal year for the purpose of making grants under section 2601(a) to eligible areas whose application under section 2605(b)—

(A) contains a report concerning the dissemination of emergency relief funds under subsection (a) and the plan for utilization of such funds;

(B) demonstrates the severe need in such area for supplemental financial assistance to combat the HIV epidemic;

(C) demonstrates the existing commitment of local resources of the area, both financial and in-kind, to combat the HIV epidemic;

(D) demonstrates the ability of the area to utilize such supplemental financial resources in a manner that is immediately responsive and cost effective; and

(E) demonstrates that resources will be allocated in accordance with the local demographic incidence of AIDS

including appropriate allocations for services for infants, children, women, and families with HIV disease.

(2) REMAINDER OF AMOUNTS.—In determining the amount of funds to be obligated under paragraph (1), the Secretary shall include amounts that are not paid to the eligible areas under expedited procedures under section 2603(a)(2) as a result of—

(A) the failure of any eligible area to submit an application under section 2605(c); or

(B) any eligible area informing the Secretary that such eligible area does not intend to expend the full amount of its grant under such section.

(3) AMOUNT OF GRANT.—The amount of each grant made for purposes of this subsection shall be determined by the Secretary based on the application submitted by the eligible area under section 2605(b).

(4) FAILURE TO SUBMIT.—

(A) IN GENERAL.—The failure of an eligible area to submit an application for an expedited grant under section 2603(a)(2) shall not result in such area being ineligible for a grant under this subsection.

(B) APPLICATION.—The application of an eligible area submitted under section 2605(b) shall contain the assurances required under subsection (a) of such section if such eligible area fails to submit an application for an expedited grants¹ under section 2603(a)(2).

SEC. 2604. [300ff-14] USE OF AMOUNTS.

(a) REQUIREMENTS.—The Secretary may not make a grant under section 2601(a) to the chief elected official of an eligible area unless such political subdivision agrees that—

(1) subject to paragraph (2), the allocation of funds and services within the eligible area will be made in accordance with the priorities established, pursuant to section 2602(b)(3)(A), by the HIV health services planning council that serves such eligible area; and

(2) funds provided under section 2601 will be expended only for the purposes described in subsections (b) and (c).

(b) PRIMARY PURPOSES.—

(1) IN GENERAL.—The chief elected official shall use amounts received under a grant under section 2601 to provide direct financial assistance to entities described in paragraph (2) for the purpose of delivering or enhancing HIV-related—

(A) outpatient and ambulatory health and support services, including case management and comprehensive treatment services, for individuals and families with HIV disease; and

(B) inpatient case management services that prevent unnecessary hospitalization or that expedite discharge, as medically appropriate, from inpatient facilities.

(2) APPROPRIATE ENTITIES.—

(A) IN GENERAL.—Subject to subparagraph (B), direct financial assistance may be provided under paragraph (1)

¹ So in original. See Public Law 101-381. Probably should be "grant".

to public or nonprofit private entities, including hospitals (which may include Department of Veterans Affairs facilities), community-based organizations, hospices, ambulatory care facilities, community health centers, migrant health centers, and homeless health centers.

(B) PRIORITY.—In providing direct financial assistance under paragraph (1) the chief elected official shall give priority to entities that are currently participating in Health Resources and Services Administration HIV health care demonstration projects.

(c) LIMITED EXPENDITURES FOR PERSONNEL NEEDS.—

(1) IN GENERAL.—A chief elected official, in accordance with paragraph (3), may use not to exceed 10 percent of amounts received under a grant under section 2601 to provide financial assistance or services, for the purposes described in paragraph (2), to any public or nonprofit private entity, including hospitals (which may include Veterans Administration facilities¹), nursing homes, subacute and transitional care facilities, and hospices that—

(A) provide HIV-related care or services to a disproportionate share of low-income individuals and families with HIV disease;

(B) incur uncompensated costs in the provision of such care or services to such individuals and families;

(C) have established, and agree to implement, a plan to evaluate the utilization of services provided in the care of individuals and families with HIV disease; and

(D) have established a system designed to ensure that such individuals and families are referred to the most medically appropriate level of care as soon as such referral is medically indicated.

(2) USE.—A chief elected official may use amounts referred to in paragraph (1) to—

(A) provide direct financial assistance to institutions and entities of the type referred to in such paragraph to assist such institutions and entities in recruiting or training and paying compensation to qualified personnel determined, under paragraph (3), to be necessary by the HIV health services planning council, specifically for the care of individuals with HIV disease; or

(B) in lieu of providing direct financial assistance, make arrangements for the provision of the services of such qualified personnel to such institutions and entities.

(3) REQUIREMENT OF DETERMINATION BY COUNCIL.—A chief elected official shall not use any of the amounts received under a grant under section 2601(a) to provide assistance or services under paragraph (2) unless the HIV health services planning council of the eligible area has made a determination that, with respect to the care of individuals with HIV disease—

(A) a shortage of specific health, mental health or support service personnel exists within specific institutions or entities in the eligible area;

(B) the shortage of such personnel has resulted in the inappropriate utilization of inpatient services within the area; and

(C) assistance or services provided to an institution or entity under paragraph (2), will not be used to supplant the existing resources devoted by such institution or entity to the uses described in such paragraph.

(d) **REQUIREMENT OF STATUS AS MEDICAID PROVIDER.—**

(1) **PROVISION OF SERVICE.**—Subject to paragraph (2), the Secretary may not make a grant under section 2601(a) for the provision of services under this section in a State unless, in the case of any such service that is available pursuant to the State plan approved under title XIX of the Social Security Act for the State—

(A) the political subdivision involved will provide the service directly, and the political subdivision has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(B) the political subdivision will enter into an agreement with a public or nonprofit private entity under which the entity will provide the service, and the entity has entered into such a participation agreement and is qualified to receive such payments.

(2) **WAIVER.—**

(A) **IN GENERAL.**—In the case of an entity making an agreement pursuant to paragraph (1)(B) regarding the provision of services, the requirement established in such paragraph shall be waived by the HIV health services planning council for the eligible area if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(B) **DETERMINATION.**—A determination by the HIV health services planning council of whether an entity referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the entity accepts voluntary donations for the purpose of providing services to the public.

(e) **ADMINISTRATION AND PLANNING.**—The chief executive officer of an eligible area shall not use in excess of 5 percent of amounts received under a grant awarded under this part for administration, accounting, reporting, and program oversight functions.

(f) **CONSTRUCTION.**—A State may not use amounts received under a grant awarded under this part to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or to make cash payments to intended recipients of services.

SEC. 2605. [300ff-15] APPLICATION.

(a) **IN GENERAL.**—To be eligible to receive a grant under section 2601, an eligible area shall prepare and submit to the Secretary an application at such time, in such form, and containing

such information as the Secretary shall require, including assurances adequate to ensure—

(1)(A) that funds received under a grant awarded under this part will be utilized to supplement not supplant State funds made available in the year for which the grant is awarded to provide HIV-related services to individuals with HIV disease;

(B) that the political subdivisions within the eligible area will maintain the level of expenditures by such political subdivisions for HIV-related services for individuals with HIV disease at a level that is equal to the level of such expenditures by such political subdivisions for the 1-year period preceding the first fiscal year for which a grant is received by the eligible area; and

(C) that political subdivisions within the eligible area will not use funds received under a grant awarded under this part in maintaining the level of expenditures for HIV-related services as required in subparagraph (B);

(2) that the eligible area has an HIV health services planning council and has entered into intergovernmental agreements pursuant to section 2602, and has developed or will develop the comprehensive plan in accordance with section 2602(b)(3)(B);

(3) that entities within the eligible area that will receive funds under a grant provided under section 2601(a) shall participate in an established HIV community-based continuum of care if such continuum exists within the eligible area;

(4) that funds received under a grant awarded under this part will not be utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(B) by an entity that provides health services on a pre-paid basis; and

(5) to the maximum extent practicable, that—

(A) HIV health care and support services provided with assistance made available under this part will be provided without regard—

(i) to the ability of the individual to pay for such services; and

(ii) to the current or past health condition of the individual to be served;

(B) such services will be provided in a setting that is accessible to low-income individuals with HIV-disease; and

(C) a program of outreach will be provided to low-income individuals with HIV-disease to inform such individuals of such services.

(b) **ADDITIONAL APPLICATION.**—An eligible area that desires to receive a grant under section 2603(b) shall prepare and submit to the Secretary an additional application at such time, in such form, and containing such information as the Secretary shall require, in-

cluding the information required under such subsection and information concerning—

(1) the number of individuals to be served within the eligible area with assistance provided under the grant;

(2) demographic data on the population of such individuals;

(3) the average cost of providing each category of HIV-related health services and the extent to which such cost is paid by third-party payors; and

(4) the aggregate amounts expended for each such category of services.

(c) DATE CERTAIN FOR SUBMISSION.—

(1) REQUIREMENT.—Except as provided in paragraph (2), to be eligible to receive a grant under section 2601(a) for a fiscal year, an application under subsection (a) shall be submitted not later than 45 days after the date on which appropriations are made under section 2608 for the fiscal year.

(2) EXCEPTION.—The Secretary may extend the time for the submission of an application under paragraph (1) for a period of not to exceed 60 days if the Secretary determines that the eligible area has made a good faith effort to comply with the requirement of such paragraph but has otherwise been unable to submit its application.

(3) DISTRIBUTION BY SECRETARY.—Not later than 45 days after receiving an application that meets the requirements of subsection (a) from an eligible area, the Secretary shall distribute to such eligible area the amounts awarded under the grant for which the application was submitted.

(4) REDISTRIBUTION.—Any amounts appropriated in any fiscal year under this part and not obligated to an eligible entity as a result of the failure of such entity to submit an application shall be redistributed by the Secretary to other eligible entities in proportion to the original grants made to such eligible areas under 2601(a).

(d) REQUIREMENTS REGARDING IMPOSITION OF CHARGES FOR SERVICES.—

(1) IN GENERAL.—The Secretary may not make a grant under section 2601 to an eligible area unless the eligible area provides assurances that in the provision of services with assistance provided under the grant—

(A) in the case of individuals with an income less than or equal to 100 percent of the official poverty line, the provider will not impose charges on any such individual for the provision of services under the grant;

(B) in the case of individuals with an income greater than 100 percent of the official poverty line, the provider—

(i) will impose a charge on each such individual for the provision of such services; and

(ii) will impose the charge according to a schedule of charges that is made available to the public;

(C) in the case of individuals with an income greater than 100 percent of the official poverty line and not exceeding 200 percent of such poverty line, the provider will not, for any calendar year, impose charges in an amount

exceeding 5 percent of the annual gross income of the individual involved;

(D) in the case of individuals with an income greater than 200 percent of the official poverty line and not exceeding 300 percent of such poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 7 percent of the annual gross income of the individual involved; and

(E) in the case of individuals with an income greater than 300 percent of the official poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 10 percent of the annual gross income of the individual involved.

(2) **ASSESSMENT OF CHARGE.**—With respect to compliance with the assurance made under paragraph (1), a grantee or entity receiving assistance under this part may, in the case of individuals subject to a charge for purposes of such paragraph—

(A) assess the amount of the charge in the discretion of the grantee, including imposing only a nominal charge for the provision of services, subject to the provisions of such paragraph regarding public schedules and regarding limitations on the maximum amount of charges; and

(B) take into consideration the medical expenses of individuals in assessing the amount of the charge, subject to such provisions.

(3) **APPLICABILITY OF LIMITATION ON AMOUNT OF CHARGE.**—The Secretary may not make a grant under section 2601 to an eligible area unless the eligible area agrees that the limitations established in subparagraphs (C), (D) and (E) of paragraph (1) regarding the imposition of charges for services applies to the annual aggregate of charges imposed for such services, without regard to whether they are characterized as enrollment fees, premiums, deductibles, cost sharing, copayments, coinsurance, or other charges.

(4) **WAIVER REGARDING SECONDARY AGREEMENTS.**—The requirements established in paragraphs (1) through (3) shall be waived in accordance with section 2604(d)(2).

SEC. 2606. [300ff-16] TECHNICAL ASSISTANCE.

The Administrator of the Health Resources and Services Administration may, beginning on the date of enactment of this title, provide technical assistance to assist entities in complying with the requirements of this part in order to make such entities eligible to receive a grant under this part.

SEC. 2607. [300ff-17] DEFINITIONS.

For purposes of this part:

(1) **ELIGIBLE AREA.**—The term “eligible area” means a metropolitan area described in section 2601(a).

(2) **METROPOLITAN AREA.**—The term “metropolitan area” means an area referred to in the HIV/AIDS Surveillance Report of the Centers for Disease Control and Prevention as a metropolitan area.

SEC. 2608. [300ff-18] AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to make grants under this part, \$275,000,000 in each of the fiscal years 1991 and 1992, and such sums as may be necessary in each of the fiscal years 1993 through 1995.

PART B—CARE GRANT PROGRAM**SEC. 2611. [300ff-21] GRANTS.**

The Secretary shall, subject to the availability of appropriations, make grants to States to enable such States to improve the quality, availability and organization of health care and support services for individuals and families with HIV disease.

SEC. 2612. [300ff-22] GENERAL USE OF GRANTS.

(a) IN GENERAL.—A State may use amounts provided under grants made under this part—

(1) to establish and operate HIV care consortia within areas most affected by HIV disease that shall be designed to provide a comprehensive continuum of care to individuals and families with HIV disease in accordance with section 2613;

(2) to provide home- and community-based care services for individuals with HIV disease in accordance with section 2614;

(3) to provide assistance to assure the continuity of health insurance coverage for individuals with HIV disease in accordance with section 2615; and

(4) to provide treatments, that have been determined to prolong life or prevent serious deterioration of health, to individuals with HIV disease in accordance with section 2616.

(b) INFANTS AND WOMEN, ETC.—A State shall use not less than 15 percent of funds allocated under this part to provide health and support services to infants, children, women, and families with HIV disease.

SEC. 2613. [300ff-23] GRANTS TO ESTABLISH HIV CARE CONSORTIA.

(a) CONSORTIA.—A State may use amounts provided under a grant awarded under this part to provide assistance under section 2612(a)(1) to an entity that—

(1) is an association of one or more public, and one or more nonprofit private, health care and support service providers and community based organizations operating within areas determined by the State to be most affected by HIV disease; and

(2) agrees to use such assistance for the planning, development and delivery, through the direct provision of services or through entering into agreements with other entities for the provision of such services, of comprehensive outpatient health and support services for individuals with HIV disease, that may include—

(A) essential health services such as case management services, medical, nursing, and dental care, diagnostics, monitoring, and medical follow-up services, mental health, developmental, and rehabilitation services, home health and hospice care; and

(B) essential support services such as transportation services, attendant care, homemaker services, day or res-

pite care, benefits advocacy, advocacy services provided through public and nonprofit private entities, and services that are incidental to the provision of health care services for individuals with HIV disease including nutrition services, housing referral services, and child welfare and family services (including foster care and adoption services).

An entity or entities of the type described in this subsection shall hereinafter be referred to in this title as a "consortium" or "consortia".

(b) ASSURANCES.—

(1) REQUIREMENT.—To receive assistance from a State under subsection (a), an applicant consortium shall provide the State with assurances that—

(A) within any locality in which such consortium is to operate, the populations and subpopulations of individuals and families with HIV disease have been identified by the consortium;

(B) the service plan established under subsection (c)(2) by such consortium addresses the special care and service needs of the populations and subpopulations identified under subparagraph (A); and

(C) except as provided in paragraph (2), the consortium will be a single coordinating entity that will integrate the delivery of services among the populations and subpopulations identified under subparagraph (A).

(2) EXCEPTION.—Subparagraph (C) of paragraph (1) shall not apply to any applicant consortium that the State determines will operate in a community or locality in which it has been demonstrated by the applicant consortium that—

(A) subpopulations exist within the community to be served that have unique service requirements; and

(B) such unique service requirements cannot be adequately and efficiently addressed by a single consortium serving the entire community or locality.

(c) APPLICATION.—

(1) IN GENERAL.—To receive assistance from the State under subsection (a), a consortium shall prepare and submit to the State, an application that—

(A) demonstrates that the consortium includes agencies and community-based organizations—

(i) with a record of service to populations and subpopulations with HIV disease requiring care within the community to be served; and

(ii) that are representative of populations and subpopulations reflecting the local incidence of HIV and that are located in areas in which such populations reside;

(B) demonstrates that the consortium has carried out an assessment of service needs within the geographic area to be served and, after consultation with the entities described in paragraph (2), has established a plan to ensure the delivery of services to meet such identified needs that shall include—

(i) assurances that service needs will be addressed through the coordination and expansion of existing programs before new programs are created;

(ii) assurances that, in metropolitan areas, the geographic area to be served by the consortium corresponds to the geographic boundaries of local health and support services delivery systems to the extent practicable;

(iii) assurances that, in the case of services for individuals residing in rural areas, the applicant consortium shall deliver case management services that link available community support services to appropriate specialized medical services; and

(iv) assurances that the assessment of service needs and the planning of the delivery of services will include participation by individuals with HIV disease;

(C) demonstrates that adequate planning has occurred to meet the special needs of families with HIV disease, including family centered care;

(D) demonstrates that the consortium has created a mechanism to evaluate periodically—

(i) the success of the consortium in responding to identified needs; and

(ii) the cost-effectiveness of the mechanisms employed by the consortium to deliver comprehensive care; and

(E) demonstrates that the consortium will report to the State the results of the evaluations described in subparagraph (D) and shall make available to the State or the Secretary, on request, such data and information on the program methodology that may be required to perform an independent evaluation.

(2) CONSULTATION.—In establishing the plan required under paragraph (1)(B), the consortium shall consult with—

(A)(i) the public health agency that provides or supports ambulatory and outpatient HIV-related health care services within the geographic area to be served; or

(ii) in the case of a public health agency that does not directly provide such HIV-related health care services such agency shall consult with an entity or entities that directly provide ambulatory and outpatient HIV-related health care services within the geographic area to be served; and

(B) not less than one community-based organization that is organized solely for the purpose of providing HIV-related support services to individuals with HIV disease.

The organization to be consulted under subparagraph (B) shall be at the discretion of the applicant consortium.

(d) DEFINITION.—As used in this part, the term “family centered care” means the system of services described in this section that is targeted specifically to the special needs of infants, children, women, and families. Family centered care shall be based on a partnership between parents, professionals, and the community designed to ensure an integrated, coordinated, culturally sensitive,

and community-based continuum of care for children, women, and families with HIV disease.

(e) PRIORITY.—In providing assistance under subsection (a), the State shall, among applicants that meet the requirements of this section, give priority—

(1) first to consortia that are receiving assistance from the Health Resources and Services Administration for adult and pediatric HIV-related care demonstration projects; and then

(2) to any other existing HIV care consortia.

SEC. 2614. [300ff-24] GRANTS FOR HOME- AND COMMUNITY-BASED CARE.

(a) USES.—A State may use amounts provided under a grant awarded under this part to make grants under section 2612(a)(2) to entities to—

(1) provide home- and community-based health services for individuals with HIV disease pursuant to written plans of care prepared by a case management team, that shall include appropriate health care professionals, in such State for providing such services to such individuals;

(2) provide outreach services to individuals with HIV disease, including those individuals in rural areas; and

(3) provide for the coordination of the provision of services under this section with the provision of HIV-related health services provided by public and private entities.

(b) PRIORITY.—In awarding grants under subsection (a), a State shall give priority to entities that provide assurances to the State that—

(1) such entities will participate in HIV care consortia if such consortia exist within the State; and

(2) such entities will utilize amounts provided under such grants for the provision of home- and community-based services to low-income individuals with HIV disease.

(c) DEFINITION.—As used in this part, the term “home- and community-based health services”—

(1) means, with respect to an individual with HIV disease, skilled health services furnished to the individual in the individual’s home pursuant to a written plan of care established by a case management team, that shall include appropriate health care professionals, for the provision of such services and items described in paragraph (2);

(2) includes—

(A) durable medical equipment;

(B) homemaker or home health aide services and personal care services furnished in the home of the individual;

(C) day treatment or other partial hospitalization services;

(D) home intravenous and aerosolized drug therapy (including prescription drugs administered as part of such therapy);

(E) routine diagnostic testing administered in the home of the individual; and

(F) appropriate mental health, developmental, and rehabilitation services; and

(3) does not include—

(A) inpatient hospital services; and

(B) nursing home and other long term care facilities.

SEC. 2615. [300ff-25] CONTINUUM OF HEALTH INSURANCE COVERAGE.

(a) **IN GENERAL.**—A State may use amounts received under a grant awarded under this part to establish a program of financial assistance under section 2612(a)(3) to assist eligible low-income individuals with HIV disease in—

(1) maintaining a continuity of health insurance; or

(2) receiving medical benefits under a health insurance program, including risk-pools.

(b) **LIMITATIONS.**—Assistance shall not be utilized under subsection (a)—

(1) to pay any costs associated with the creation, capitalization, or administration of a liability risk pool (other than those costs paid on behalf of individuals as part of premium contributions to existing liability risk pools); and

(2) to pay any amount expended by a State under title XIX of the Social Security Act.

SEC. 2616. [300ff-26] PROVISION OF TREATMENTS.

(a) **IN GENERAL.**—A State may use amounts provided under a grant awarded under this part to establish a program under section 2612(a)(4) to provide treatments that have been determined to prolong life or prevent the serious deterioration of health arising from HIV disease in eligible individuals.

(b) **ELIGIBLE INDIVIDUAL.**—To be eligible to receive assistance from a State under this section an individual shall—

(1) have a medical diagnosis of HIV disease; and

(2) be a low-income individual, as defined by the State.

(c) **STATE DUTIES.**—In carrying out this section the State shall—

(1) determine, in accordance with guidelines issued by the Secretary, which treatments are eligible to be included under the program established under this section;

(2) provide assistance for the purchase of treatments determined to be eligible under paragraph (1), and the provision of such ancillary devices that are essential to administer such treatments;

(3) provide outreach to individuals with HIV disease, and as appropriate to the families of such individuals; and

(4) facilitate access to treatments for such individuals.

SEC. 2617. [300ff-27] STATE APPLICATION.

(a) **IN GENERAL.**—The Secretary shall not make a grant to a State under this part for a fiscal year unless the State prepares and submits, to the Secretary, an application at such time, in such form, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

(b) **DESCRIPTION OF INTENDED USES AND AGREEMENTS.**—The application submitted under subsection (a) shall contain—

(1) a detailed description of the HIV-related services provided in the State to individuals and families with HIV disease during the year preceding the year for which the grant is requested, and the number of individuals and families receiving such services, that shall include—

(A) a description of the types of programs operated or funded by the State for the provision of HIV-related services during the year preceding the year for which the grant is requested and the methods utilized by the State to finance such programs;

(B) an accounting of the amount of funds that the State has expended for such services and programs during the year preceding the year for which the grant is requested; and

(C) information concerning—

(i) the number of individuals to be served with assistance provided under the grant;

(ii) demographic data on the population of the individuals to be served;

(iii) the average cost of providing each category of HIV-related health services and the extent to which such cost is paid by third-party payors; and

(iv) the aggregate amounts expended for each such category of services;

(2) a comprehensive plan for the organization and delivery of HIV health care and support services to be funded with assistance received under this part that shall include a description of the purposes for which the State intends to use such assistance, including—

(A) the services and activities to be provided and an explanation of the manner in which the elements of the program to be implemented by the State with such assistance will maximize the quality of health and support services available to individuals with HIV disease throughout the State; and

(B) a description of the manner in which services funded with assistance provided under this part will be coordinated with other available related services for individuals with HIV disease; and

(3) an assurance by the State that—

(A) the public health agency that is administering the grant for the State will conduct public hearings concerning the proposed use and distribution of the assistance to be received under this part;

(B) the State will—

(i) to the maximum extent practicable, ensure that HIV-related health care and support services delivered pursuant to a program established with assistance provided under this part will be provided without regard to the ability of the individual to pay for such services and without regard to the current or past health condition of the individual with HIV disease;

(ii) ensure that such services will be provided in a setting that is accessible to low-income individuals with HIV disease;

(iii) provide outreach to low-income individuals with HIV disease to inform such individuals of the services available under this part; and

(iv) in the case of a State that intends to use amounts provided under the grant for purposes described in 2615¹, submit a plan to the Secretary that demonstrates that the State has established a program that assures that—

(I) such amounts will be targeted to individuals who would not otherwise be able to afford health insurance coverage; and

(II) income, asset, and medical expense criteria will be established and applied by the State to identify those individuals who qualify for assistance under such program, and information concerning such criteria shall be made available to the public;

(C) the State will provide for periodic independent peer review to assess the quality and appropriateness of health and support services provided by entities that receive funds from the State under this part;

(D) the State will permit and cooperate with any Federal investigations undertaken regarding programs conducted under this part;

(E) the State will maintain HIV-related activities at a level that is equal to not less than the level of such expenditures by the State for the 1-year period preceding the fiscal year for which the State is applying to receive a grant under this part; and

(F) the State will ensure that grant funds are not utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service—

(i) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(ii) by an entity that provides health services on a prepaid basis.

(c) REQUIREMENTS REGARDING IMPOSITION OF CHARGES FOR SERVICES.—

(1) IN GENERAL.—The Secretary may not make a grant under section 2611 to a State unless the State provides assurances that in the provision of services with assistance provided under the grant—

(A) in the case of individuals with an income less than or equal to 100 percent of the official poverty line, the provider will not impose charges on any such individual for the provision of services under the grant;

(B) in the case of individuals with an income greater than 100 percent of the official poverty line, the provider—

(i) will impose charges on each such individual for the provision of such services; and

(ii) will impose charges according to a schedule of charges that is made available to the public;

¹ So in original. Probably should be "section 2615".

(C) in the case of individuals with an income greater than 100 percent of the official poverty line and not exceeding 200 percent of such poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 5 percent of the annual gross income of the individual involved;

(D) in the case of individuals with an income greater than 200 percent of the official poverty line and not exceeding 300 percent of such poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 7 percent of the annual gross income of the individual involved; and

(E) in the case of individuals with an income greater than 300 percent of the official poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 10 percent of the annual gross income of the individual involved.

(2) ASSESSMENT OF CHARGE.—With respect to compliance with the assurance made under paragraph (1), a grantee under this part may, in the case of individuals subject to a charge for purposes of such paragraph—

(A) assess the amount of the charge in the discretion of the grantee, including imposing only a nominal charge for the provision of services, subject to the provisions of such paragraph regarding public schedules regarding limitation on the maximum amount of charges; and

(B) take into consideration the medical expenses of individuals in assessing the amount of the charge, subject to such provisions.

(3) APPLICABILITY OF LIMITATION ON AMOUNT OF CHARGE.—The Secretary may not make a grant under section 2611 unless the applicant of the grant agrees that the limitations established in subparagraphs (C), (D), and (E) of paragraph (1) regarding the imposition of charges for services applies to the annual aggregate of charges imposed for such services, without regard to whether they are characterized as enrollment fees, premiums, deductibles, cost sharing, copayments, coinsurance, or other charges.

(4) WAIVER.—

(A) IN GENERAL.—The State shall waive the requirements established in paragraphs (1) through (3) in the case of an entity that does not, in providing health care services, impose a charge or accept reimbursement from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(B) DETERMINATION.—A determination by the State of whether an entity referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the entity accepts voluntary donations regarding the provision of services to the public.

(d) REQUIREMENT OF MATCHING FUNDS REGARDING STATE ALLOTMENTS.—

(1) IN GENERAL.—In the case of any State to which the criterion described in paragraph (3) applies, the Secretary may not make a grant under this part unless the State agrees that, with respect to the costs to be incurred by the State in carrying out the program for which the grant was awarded, the State will, subject to subsection (b)(2), make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount equal to—

(A) for the first fiscal year of payments under the grant, not less than $16\frac{2}{3}$ percent of such costs (\$1 for each \$5 of Federal funds provided in the grant);

(B) for any second fiscal year of such payments, not less than 20 percent of such costs (\$1 for each \$4 of Federal funds provided in the grant);

(C) for any third fiscal year of such payments, not less than 25 percent of such costs (\$1 for each \$3 of Federal funds provided in the grant);

(D) for any fourth fiscal year of such payments, not less than $33\frac{1}{3}$ percent of such costs (\$1 for each \$2 of Federal funds provided in the grant); and

(E) for any subsequent fiscal year of such payments, not less than $33\frac{1}{3}$ percent of such costs (\$1 for each \$2 of Federal funds provided in the grant).

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

(A) IN GENERAL.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) INCLUSION OF CERTAIN AMOUNTS.—

(i) In making a determination of the amount of non-Federal contributions made by a State for purposes of paragraph (1), the Secretary shall, subject to clause (ii), include any non-Federal contributions provided by the State for HIV-related services, without regard to whether the contributions are made for programs established pursuant to this title;

(ii) In making a determination for purposes of clause (i), the Secretary may not include any non-Federal contributions provided by the State as a condition of receiving Federal funds under any program under this title (except for the program established in this part) or under other provisions of law.

(3) APPLICABILITY OF REQUIREMENT.—

(A) NUMBER OF CASES.—A State referred to in paragraph (1) is any State for which the number of cases of acquired immune deficiency syndrome reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the period described in subparagraph

(B) constitutes in excess of 1 percent of the aggregate num-

ber of such cases reported to and confirmed by the Director for such period for the United States.

(B) PERIOD OF TIME.—The period referred to in subparagraph (A) is the 2-year period preceding the fiscal year for which the State involved is applying to receive a grant under subsection (a).

(C) PUERTO RICO.—For purposes of paragraph (1), the number of cases of acquired immune deficiency syndrome reported and confirmed for the Commonwealth of Puerto Rico for any fiscal year shall be deemed to be less than 1 percent.

(4) DIMINISHED STATE CONTRIBUTION.—With respect to a State that does not make available the entire amount of the non-Federal contribution referred to in paragraph (1), the State shall continue to be eligible to receive Federal funds under a grant under this part, except that the Secretary in providing Federal funds under the grant shall provide such funds (in accordance with the ratios prescribed in paragraph (1)) only with respect to the amount of funds contributed by such State.

SEC. 2618. [300ff-28] DISTRIBUTION OF FUNDS.

(a) SPECIAL PROJECTS OF A NATIONAL SIGNIFICANCE.—

(1) IN GENERAL.—Of the amount appropriated under section 2620 for each fiscal year, the Secretary shall use not to exceed 10 percent of such amount to establish and administer a special projects of national significance program to award direct grants to public and nonprofit private entities including community-based organizations to fund special programs for the care and treatment of individuals with HIV disease.

(2) GRANTS.—The Secretary shall award grants under subsection (a) based on—

(A) the need to assess the effectiveness of a particular model for the care and treatment of individuals with HIV disease;

(B) the innovative nature of the proposed activity; and

(C) the potential replicability of the proposed activity in other similar localities or nationally.

(3) SPECIAL PROJECTS.—Special projects of a national significance may include those that are designed to—

(A) establish a system designed to increase the number of health care facilities willing and able to serve low-income individuals and families with HIV disease;

(B) deliver drug abuse treatment and HIV health care services at a single location, through either an outpatient or residential facility;

(C) provide support and respite care for participants in family-based care networks critical to the delivery of comprehensive HIV care in the minority community;

(D) deliver an enhanced spectrum of comprehensive health care and support services to underserved hemophilia populations, including minorities and those in rural and underserved areas, utilizing established networks of

hemophilia diagnostic and treatment centers and community-based outreach systems;

(E) deliver HIV health care and support services to Indians with HIV disease and their families;

(F) improve the provision of HIV health care and support services to individuals and families with HIV disease located in rural areas;

(G) deliver HIV health care and support services to homeless individuals and families with HIV disease; and

(H) deliver HIV health care and support services to individuals with HIV disease who are incarcerated.

(b) AMOUNT OF GRANT TO STATE.—

(1) MINIMUM ALLOTMENT.—Subject to the extent of amounts made available under section 2620, the amount of a grant to be made under this part for—

(A) each of the several States and the District of Columbia for a fiscal year shall be the greater of—

(i) \$100,000, and

(ii) an amount determined under paragraph (2);

and

(B) each territory of the United States, as defined in paragraph 3¹, shall be an amount determined under paragraph (2).

(2) DETERMINATION.—

(A) FORMULA.—The amount referred to in paragraph (1)(A)(ii) for a State and paragraph (1)(B) for a territory of the United States shall be the product of—

(i) an amount equal to the amount appropriated under section 2620 for the fiscal year involved; and

(ii) the ratio of the distribution factor for the State or territory to the sum of the distribution factors for all the States or territories.

(B) DISTRIBUTION FACTOR.—As used in subparagraph (A)(ii), the term “distribution factor” means—

(i) in the case of a State, the product of—

(I) the number of cases of acquired immune deficiency syndrome in the State, as indicated by the number of cases reported to and confirmed by the Secretary for the 2 most recent fiscal years for which such data are available; and

(II) the cube root of the ratio (based on the most recent available data) of—

(aa) the average per capita income of individuals in the United States (including the territories); to

(bb) the average per capita income of individuals in the State; and

(ii) in the case of a territory of the United States the number of additional cases of such syndrome in the specific territory, as indicated by the number of cases reported to and confirmed by the Secretary for

¹ So in original. See Public Law 101-381. Probably should be “(3)”.

the 2 most recent fiscal years for which such data is available.

(3) DEFINITIONS.—As used in this subsection—

(A) the term “State” means each of the 50 States, the District of Columbia and the Commonwealth of Puerto Rico; and

(B) the term “territory of the United States” means the Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Republic of the Marshall Islands.

(c) ALLOCATION OF ASSISTANCE BY STATES.—

(1) CONSORTIA.—In a State that has reported 1 percent or more of all AIDS cases reported to and confirmed by the Centers for Disease Control and Prevention in all States, not less than 50 percent of the amount received by the State under a grant awarded under this part shall be utilized for the creation and operation of community-based comprehensive care consortia under section 2613, in those areas within the State in which the largest number of individuals with HIV disease reside.

(2) ALLOWANCES.—Prior to allocating assistance under this subsection, a State shall consider the unmet needs of those areas that have not received financial assistance under part A.

(3) PLANNING AND EVALUATIONS.—A State may not use in excess of 5 percent of amounts received under a grant awarded under this part for planning and evaluation activities.

(4) ADMINISTRATION.—A State may not use in excess of 5 percent of amounts received under a grant awarded under this part for administration, accounting, reporting, and program oversight functions.

(5) CONSTRUCTION.—A State may not use amounts received under a grant awarded under this part to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or to make cash payments to intended recipients of services.

(d) EXPEDITED DISTRIBUTION.—

(1) IN GENERAL.—Not less than 75 percent of the amounts received under a grant awarded to a State under this part shall be obligated to specific programs and projects and made available for expenditure not later than—

(A) in the case of the first fiscal year for which amounts are received, 150 days after the receipt of such amounts by the State; and

(B) in the case of succeeding fiscal years, 120 days after the receipt of such amounts by the State.

(2) PUBLIC COMMENT.—Within the time periods referred to in paragraph (1), the State shall invite and receive public comment concerning methods for the utilization of such amounts.

(e) REALLOCATION.—Any amounts appropriated in any fiscal year and made available to a State under this part that have not been obligated as described in subsection (d) shall be repaid to the Secretary and reallocated to other States in proportion to the original grants made to such States.

SEC. 2619. [300ff-29] TECHNICAL ASSISTANCE.

The Secretary may provide technical assistance in administering and coordinating the activities authorized under section 2612.

SEC. 2620. [300ff-30] AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to make grants under this part, \$275,000,000 in each of the fiscal years 1991 and 1992, and such sums as may be necessary in each of the fiscal years 1993 through 1995.

PART C—EARLY INTERVENTION SERVICES**Subpart I—Formula Grants for States****SEC. 2641. [300ff-41] ESTABLISHMENT OF PROGRAM.**

(a) **ALLOTMENTS FOR STATES.**—For the purposes described in subsection (b), the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator of the Health Resources and Services Administration, shall for each of the fiscal years 1991 through 1995 make an allotment for each State in an amount determined in accordance with section 2649. The Secretary shall make payments, as grants, to each State from the allotment for the State for the fiscal year involved if the Secretary approves for the fiscal year an application submitted by the State pursuant to section 2665.

(b) **PURPOSES OF GRANTS.**—

(1) **IN GENERAL.**—The Secretary may not make a grant under subsection (a) unless the State involved agrees to expend the grant for the purposes of providing, on an outpatient basis, each of the early intervention services specified in paragraph (2) with respect to HIV disease.

(2) **SPECIFICATION OF EARLY INTERVENTION SERVICES.**—The early intervention services referred to in paragraph (1) are—

(A) counseling individuals with respect to HIV disease in accordance with section 2662;

(B) testing individuals with respect to such disease, including tests to confirm the presence of the disease, tests to diagnose the extent of the deficiency in the immune system, and tests to provide information on appropriate therapeutic measures for preventing and treating the deterioration of the immune system and for preventing and treating conditions arising from the disease;

(C) referrals described in paragraph (3);

(D) other clinical and diagnostic services with respect to HIV disease, and periodic medical evaluations of individuals with the disease; and

(E) providing the therapeutic measures described in subparagraph (B).

(3) **REFERRALS.**—The services referred to in paragraph (2)(C) are referrals of individuals with HIV disease to appropriate providers of health and support services, including, as appropriate—

(A) to entities receiving amounts under part A or B for the provision of such services;

(B) to biomedical research facilities of institutions of higher education that offer experimental treatment for such disease, or to community-based organizations or other entities that provide such treatment; or

(C) to grantees under section 2671, in the case of pregnant women.

(4) REQUIREMENT OF AVAILABILITY OF ALL EARLY INTERVENTION SERVICES THROUGH EACH GRANTEE.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that each of the early intervention services specified in paragraph (2) will be available through the State. With respect to compliance with such agreement, a State may expend the grant to provide the early intervention services directly, and may expend the grant to enter into agreements with public or nonprofit private entities under which the entities provide the services.

(5) OPTIONAL SERVICES.—A State receiving a grant under subsection (a)—

(A) may expend not more than 5 percent of the grant to provide early intervention services through making grants to hospitals that—

(i) for the most recent fiscal year for which the data is available, have admitted—

(I) not fewer than 250 individuals with acquired immune deficiency syndrome; or

(II) a number of such individuals constituting 20 percent of the number of inpatients of the hospital admitted during such period;

(ii) agree to offer and encourage such services with respect to inpatients of the hospitals; and

(iii) agree that subsections (c) and (d) of section 2644 will apply to the hospitals to the same extent and in the same manner as such subsections apply to entities described in such section;

(B) may expend the grant to provide outreach services to individuals who may have HIV disease, or may be at risk of the disease, and who may be unaware of the availability and potential benefits of early treatment of the disease, and to provide outreach services to health care professionals who may be unaware of such availability and potential benefits; and

(C) may, in the case of individuals who seek early intervention services from the grantee, expend the grant—

(i) for case management to provide coordination in the provision of health care services to the individuals and to review the extent of utilization of the services by the individuals; and

(ii) to provide assistance to the individuals regarding establishing the eligibility of the individuals for financial assistance and services under Federal, State, or local programs providing for health services, mental health services, social services, or other appropriate services.

(6) ALLOCATIONS.—

(A) Subject to subparagraphs (B) and (C), the Secretary may not make a grant under subsection (a) unless the State involved agrees—

(i) to expend not less than 35 percent of the grant to provide the early intervention services specified in subparagraphs (A) through (C) of paragraph (2); and

(ii) to expend not less than 35 percent of the grant to provide the early intervention services specified in subparagraphs (D) and (E) of such paragraph.

(B) With respect to compliance with the agreement under subparagraph (A), amounts reserved by a State for fiscal year 1991 for purposes of clauses (i) and (ii) of such subparagraph may be expended to provide the services specified in paragraph (5).

(C) The Secretary shall ensure that, of the amounts appropriated under section 2650 for fiscal year 1991, an amount equal to \$130,000,000 is expended to provide the early intervention services specified in subparagraphs (A) through (C) of paragraph (2).

SEC. 2642. [300ff-42] PROVISION OF SERVICES THROUGH MEDICAID PROVIDERS.

(a) **IN GENERAL.**—Subject to subsection (b), the Secretary may not make a grant under section 2641 to a State unless, in the case of any service described in subsection (b) of such section that is available pursuant to the State plan approved under title XIX of the Social Security Act for the State—

(1) the State will provide the service through a State entity, and the State entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(2) the State will enter into an agreement with a public or nonprofit private entity under which the entity will provide the service, and the entity has entered into such a participation agreement and is qualified to receive such payments.

(b) **WAIVER REGARDING CERTAIN SECONDARY AGREEMENTS.**—

(1) **IN GENERAL.**—In the case of an entity making an agreement pursuant to subsection (a)(2) regarding the provision of services, the requirement established in such subsection regarding a participation agreement shall be waived by the Secretary if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(2) **ACCEPTANCE OF VOLUNTARY DONATIONS.**—A determination by the Secretary of whether an entity referred to in paragraph (1) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the entity accepts voluntary donations for the purpose of providing services to the public.

SEC. 2643. [300ff-43] REQUIREMENT OF MATCHING FUNDS.

(a) **IN GENERAL.**—In the case of any State to which the criterion described in subsection (c) applies, the Secretary may not

make a grant under section 2641 unless the State agrees that, with respect to the costs to be incurred by the State in carrying out the purpose referred to in such subsection, the State will, subject to subsection (b)(2), make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount equal to—

(1) for the first fiscal year for which such criterion applies to the State, not less than $16\frac{2}{3}$ percent of such costs (\$1 for each \$5 of Federal funds provided in the grant);

(2) for any second such fiscal year, not less than 20 percent of such costs (\$1 for each \$4 of Federal funds provided in the grant);

(3) for any third such fiscal year, not less than 25 percent of such costs (\$1 for each \$3 of Federal funds provided in the grant); and

(4) for any subsequent fiscal year, not less than $33\frac{1}{3}$ percent of such costs (\$1 for each \$2 of Federal funds provided in the grant).

(b) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

(1) IN GENERAL.—Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(2) INCLUSION OF CERTAIN AMOUNTS.—

(A) In making a determination of the amount of non-Federal contributions made by a State for purposes of subsection (a), the Secretary shall, subject to subparagraph (B), include any non-Federal contributions provided by the State for HIV-related services, without regard to whether the contributions are made for programs established pursuant to this title.

(B) In making a determination for purposes of subparagraph (A), the Secretary may not include any non-Federal contributions provided by the State as a condition of receiving Federal funds under any program under this title (except for the program established in section 2641) or under other provisions of law.

(c) APPLICABILITY OF MATCHING REQUIREMENT.—

(1) PERCENTAGE OF NATIONAL NUMBER OF CASES.—

(A) The criterion referred to in subsection (a) is, with respect to a State, that the number of cases of acquired immune deficiency syndrome reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the State for the period described in subparagraph (B) constitutes more than 1 percent of the number of such cases reported to and confirmed by the Director for the United States for such period.

(B) The period referred to in subparagraph (A) is the 2-year period preceding the fiscal year for which the State involved is applying to receive a grant under section 2641.

(2) EXEMPTION.—For purposes of paragraph (1), the number of cases of acquired immune deficiency syndrome reported and confirmed for the Commonwealth of Puerto Rico for any fiscal year shall be deemed to be less than 1 percent.

(d) DIMINISHED STATE CONTRIBUTION.—With respect to a State that does not make available the entire amount of the non-Federal contribution referred to in subsection (a), the State shall continue to be eligible to receive Federal funds under a grant under section 2641, except that the Secretary in providing Federal funds under the grant shall provide such funds (in accordance with the ratios prescribed in paragraph (1)) only with respect to the amount of funds contributed by such State.

SEC. 2644. [300ff-44] OFFERING AND ENCOURAGING EARLY INTERVENTION SERVICES.

(a) IN GENERAL.—The Secretary may not make a grant under section 2641 unless, in the case of entities to which the State provides amounts from the grant for the provision of early intervention services, the State involved agrees that—

(1) if the entity is a health care provider that regularly provides treatment for sexually transmitted diseases, the entity will offer and encourage such services with respect to individuals to whom the entity provides such treatment;

(2) if the entity is a health care provider that regularly provides treatment for intravenous substance abuse, the entity will offer and encourage such services with respect to individuals to whom the entity provides such treatment;

(3) if the entity is a family planning clinic, the entity will offer and encourage such services with respect to individuals to whom the entity provides family planning services and whom the entity has reason to believe has HIV disease; and

(4) if the entity is a health care provider that provides treatment for tuberculosis, the entity will offer and encourage such services with respect to individuals to whom the entity provides such treatment.

(b) SUFFICIENCY OF AMOUNT OF GRANT.—With respect to compliance with the agreement made under subsection (a), an entity to which subsection (a) applies may be required to offer, encourage, and provide early intervention services only to the extent that the amount of the grant is sufficient to pay the costs of offering, encouraging, and providing the services.

(c) CRITERIA FOR OFFERING AND ENCOURAGING.—Subject to section 2641(b)(4), an entity to which subsection (a) applies is, for purposes of such subsection, offering and encouraging early intervention services with respect to the individuals involved if the entity—

(1) offers such services to the individuals, and encourages the individuals to receive the services, as a regular practice in the course of providing the health care involved; and

(2) provides the early intervention services only with the consent of the individuals.

SEC. 2645. [300ff-45] NOTIFICATION OF CERTAIN INDIVIDUALS RECEIVING BLOOD TRANSFUSIONS.

(a) IN GENERAL.—The Secretary may not make a grant under section 2641 unless the State involved provides assurances satisfac-

tory to the Secretary that, with respect to individuals in the State receiving, between January 1, 1978, and April 1, 1985 (inclusive), a transfusion of whole blood or a blood-clotting factor, the State will provide public education and information for the purpose of—

(1) encouraging the population of such individuals to receive early intervention services; and

(2) informing such population of any health facilities in the geographic area involved that provide such services.

(b) **RULE OF CONSTRUCTION.**—An agreement made under subsection (a) may not be construed to require that, in carrying out the activities described in such subsection, a State receiving a grant under section 2641 provide individual notifications to the individuals described in such subsection.

SEC. 2646. [300ff-46] REPORTING AND PARTNER NOTIFICATION.

(a) **REPORTING.**—The Secretary may not make a grant under section 2641 unless, with respect to testing for HIV disease, the State involved provides assurances satisfactory to the Secretary that the State will require that any entity carrying out such testing confidentially report to the State public health officer information sufficient—

(1) to perform statistical and epidemiological analyses of the incidence in the State of cases of such disease;

(2) to perform statistical and epidemiological analyses of the demographic characteristics of the population of individuals in the State who have the disease; and

(3) to assess the adequacy of early intervention services in the State.

(b) **PARTNER NOTIFICATION.**—The Secretary may not make a grant under section 2641 unless the State involved provides assurances satisfactory to the Secretary that the State will require that the public health officer of the State, to the extent appropriate in the determination of the officer, carry out a program of partner notification regarding cases of HIV disease.

(c) **RULES OF CONSTRUCTION.**—An agreement made under this section may not be construed—

(1) to require or prohibit any State from providing that identifying information concerning individuals with HIV disease is required to be submitted to the State; or

(2) to require any State to establish a requirement that entities other than the public health officer of the State are required to make the notifications referred to in subsection (b).

SEC. 2647. [300ff-47] REQUIREMENT OF STATE LAW PROTECTION AGAINST INTENTIONAL TRANSMISSION.

(a) **IN GENERAL.**—The Secretary may not make a grant under section 2641 to a State unless the chief executive officer determines that the criminal laws of the State are adequate to prosecute any HIV infected individual, subject to the condition described in subsection (b), who—

(1) makes a donation of blood, semen, or breast milk, if the individual knows that he or she is infected with HIV and in-

tends, through such donation, to expose another HIV¹ in the event that the donation is utilized;

(2) engages in sexual activity if the individual knows that he or she is infected with HIV and intends, through such sexual activity, to expose another to HIV; and

(3) injects himself or herself with a hypodermic needle and subsequently provides the needle to another person for purposes of hypodermic injection, if the individual knows that he or she is infected and intends, through the provision of the needle, to expose another to such etiologic agent in the event that the needle is utilized.

(b) **CONSENT TO RISK OF TRANSMISSION.**—The State laws described in subsection (a) need not apply to circumstances under which the conduct described in paragraphs (1) through (3) of subsection (a) if the individual who is subjected to the behavior involved knows that the other individual is infected and provides prior informed consent to the activity.

(c) **STATE CERTIFICATION WITH RESPECT TO REQUIRED LAWS.**—With respect to complying with subsection (a) as a condition of receiving a grant under section 2601², the Secretary may not require a State to enact any statute, or to issue any regulation, if the chief executive officer of the State certifies to the Secretary that the laws of the State are adequate. The existence of a criminal law of general application, which can be applied to the conduct described in paragraphs (1) through (3) of subsection (a), is sufficient for compliance with this section.

(d) **TIME LIMITATIONS WITH RESPECT TO REQUIRED LAWS.**—With respect to receiving a grant under section 2601², if a State is unable to certify compliance with subsection (a), the Secretary may make a grant to a State under such section if—

(1) for each of the fiscal years 1991 and 1992, the State provides assurances satisfactory to the Secretary that by not later than October 1, 1992, the State has³ in place or will establish the prohibitions described in subsection (a); and

(2) for fiscal year 1993 and subsequent fiscal years, the State has established such prohibitions.

SEC. 2648. [300ff-48] TESTING AND OTHER EARLY INTERVENTION SERVICES FOR STATE PRISONERS.⁴

(a) **IN GENERAL.**—In addition to grants under section 2641, the Secretary may make grants to States for the purpose of assisting the States in providing early intervention services to individuals sentenced by the State to a term of imprisonment. The Secretary may make such a grant only if the State involved requires, subject to subsection (d), that—

(1) the services be provided to such individuals; and

(2) each such individual be informed of the requirements of subsection (c) regarding testing and be informed of the results of such testing of the individual.

(b) **REQUIREMENT OF MATCHING FUNDS.**—

¹ So in original. See Public Law 101-381. Probably should be "to HIV".

² So in original. Probably should be "section 2641". See Public Law 101-381.

³ So in original. Probably should be "will have". See Public Law 101-381.

⁴ So in original. Typeface is incorrect. See section 301(b)(4) of Public Law 101-381 (104 Stat. 617).

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that, with respect to the costs to be incurred by the State in carrying out the purpose described in such subsection, the State will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount equal to—

(A) for the first fiscal year of payments under the grant, not less than \$1 for each \$2 of Federal funds provided in the grant; and

(B) for any subsequent fiscal year of such payments, not less than \$1 for each \$1 of Federal funds provided in the grant.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, and services (or portions of services) subsidized by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(c) TESTING.—The Secretary may not make a grant under subsection (a) unless—

(1) the State involved requires that, subject to subsection (d), any individual sentenced by the State to a term of imprisonment be tested for HIV disease—

(A) upon entering the State penal system; and

(B) during the 30-day period preceding the date on which the individual is released from such system;

(2) with respect to informing employees of the penal system of the results of such testing of the individual, the State—

(A) upon the request of any such employee, provides the results to the employee in any case in which the medical officer of the prison determines that there is a reasonable basis for believing that the employee has been exposed by the individual to such disease; and

(B) informs the employees of the availability to the employees of such results under the conditions described in subparagraph (A);

(3) with respect to informing the spouse of the individual of the results of such testing of the individual, the State—

(A) upon the request of the spouse, provides such results to the spouse prior to any conjugal visit and provides such results to the spouse during the period described in paragraph (1)(B); and

(B) informs the spouse of the availability to the spouse of such results under the conditions described in subparagraph (A);

(4) with respect to such testing upon entering the State penal system of such an individual who has been convicted of rape or aggravated sexual assault, the State—

(A) upon the request of the victim of the rape or assault, provides such results to the victim; and

(B) informs the victim of the availability to the victim of such results; and

(5) the State, except as provided in any of paragraphs (2) through (4), maintains the confidentiality of the results of testing for HIV disease in each prison operated by the State or with amounts provided by the State, and makes disclosures of such results only as medically necessary.

(d) DETERMINATION OF PRISONS SUBJECT TO REQUIREMENT.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that the requirement established in such subsection regarding the provision of early intervention services to inmates will apply only to inmates who are incarcerated in prisons with respect to which the State public health officer, after consultation with the chief State correctional officer, has, on the basis of the criteria described in paragraph (2), determined that the provision of such services is appropriate with respect to the public health and safety.

(2) DESCRIPTION OF CRITERIA.—The criteria to be considered for purposes of paragraph (1) are—

(A) with respect to the geographic areas in which inmates of the prison involved resided before incarceration in the prison—

(i) the severity of the epidemic of HIV disease in the areas during the period in which the inmates resided in the areas; and

(ii) the incidence, in the areas during such period, of behavior that places individuals at significant risk of developing HIV disease; and

(B) the extent to which medical examinations conducted by the State for inmates of the prison involved indicate that the inmates have engaged in such behavior.

(e) APPLICABILITY OF PROVISIONS REGARDING INFORMED CONSENT, COUNSELING, AND OTHER MATTERS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that sections 2641(b)(4), 2662, and 2664(c) will apply to the provision of early intervention services pursuant to the grant in the same manner and to the same extent as such sections apply to the provision of such services by grantees under section 2641.

(f) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(g) RULE OF CONSTRUCTION.—With respect to testing inmates of State prisons for HIV disease without the consent of the inmates, the agreements made under this section may not be construed to authorize, prohibit, or require any State to conduct such testing, except as provided in subparagraphs (A) and (B) of subsection (c)(1).

(g)¹ AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1988 through 1995.

SEC. 2649. [300ff-49] DETERMINATION OF AMOUNT OF ALLOTMENTS.

(a) MINIMUM ALLOTMENT.—Subject to the extent of amounts made available in appropriations Acts, the amount of an allotment under section 2641(a) for a State for a fiscal year shall be the greater of—

(1) \$100,000 for each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, and \$50,000 for each of the territories of the United States other than the Commonwealth of Puerto Rico; and

(2) an amount determined under subsection (b).

(b) DETERMINATION UNDER FORMULA.—The amount referred to in subsection (a)(2) is the product of—

(1) an amount equal to the amount appropriated under subsection (a) of section 2650² for the fiscal year involved; and

(2) a percentage equal to the quotient of—

(A) an amount equal to the number of cases of acquired immune deficiency syndrome reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the State involved for the most recent fiscal year for which such data is available; divided by

(B) an amount equal to the number of cases of acquired immune deficiency syndrome reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the United States for the most recent fiscal year for which such data is available.

(c) CERTAIN ALLOCATIONS BY SECRETARY.—

(1) DISCRETIONARY GRANTS TO CERTAIN STATES.—After determining the amount of an allotment under this³ subsection (a) for a fiscal year, the Secretary shall reduce the amount of the allotment of each State by 10 percent. From the amounts available as a result of such reductions, the Secretary shall, on a discretionary basis, make grants to States receiving allotments for the fiscal year involved. Such grants shall be made subject to each of the agreements and assurances required as a condition of receiving grants under section 2641.

(2) GRANTS TO CERTAIN POLITICAL SUBDIVISIONS.—

(A)(i) In the case of a State containing any political subdivision described in clause (ii), the Secretary shall, subject to subparagraph (B), make a reduction in the amount of the allotment under subsection (a) for the State for each fiscal year in an amount necessary for carrying out subparagraphs (B) and (C) with respect to the political subdivision. Any such reduction shall be in addition to the

¹ So in original. Probably should be subsection (h). Section 301(b)(3) of Public Law 101-381 (104 Stat. 615) amended section 2648 by striking subsections (a) through (f) and inserting subsections (a) through (g) without redesignating the existing subsection (g).

² So in original. Section 2650 is not divided into subsections. See section 301(a) of Public Law 101-381.

³ So in original. The word "this" probably should not appear. See section 301(a) of Public Law 101-381.

reduction required in paragraph (1) for the fiscal year involved.

(ii) The political subdivision referred to in clause (i) is any political subdivision that received a cooperative agreement from the Secretary, acting through the Director of the Centers for Disease Control and Prevention, for fiscal year 1990 for programs to provide counseling and testing with respect to acquired immune deficiency syndrome.

(B) In the case of a State described in subparagraph (A), the Secretary shall, from the amounts made available as a result of reductions under such subparagraph, make a grant each fiscal year to each political subdivision described in such subparagraph that exists in the State if the political subdivision involved agrees that the provisions of subparts II and III will apply to the political subdivision to the same extent and in the same manner as such subparts apply to entities receiving grants under section 2651(a).

(C) Grants under subparagraph (B) for a fiscal year for a political subdivision shall be provided in an amount equal to the amount received by the political subdivision in fiscal year 1990 under the cooperative agreement described in subparagraph (A).

(d) DISPOSITION OF CERTAIN FUNDS APPROPRIATED FOR ALLOTMENTS.—

(1) IN GENERAL.—Any amounts available pursuant to paragraph (2) shall, in accordance with paragraph (3), be allotted by the Secretary each fiscal year to States receiving payments under section 2641(a) for the fiscal year (other than any State referred to in paragraph (2)(C)). The Secretary shall make payments, as grants, to each such State from any such allotment for the State for the fiscal year involved.

(2) SPECIFICATION OF AMOUNTS.—The amounts referred to in paragraph (1) are any amounts that are not paid to States under section 2641(a) as a result of—

(A) the failure of any State to submit an application under section 2651;

(B) the failure, in the determination of the Secretary, of any State to prepare the application in compliance with such section or to submit the application within a reasonable period of time; or

(C) any State informing the Secretary that the State does not intend to expend the full amount of the allotment made to the State.

(3) AMOUNT OF ALLOTMENT.—The amount of an allotment under paragraph (1) for a State for a fiscal year shall be an amount equal to the product of—

(A) an amount equal to the amount available pursuant to paragraph (2) for the fiscal year involved; and

(B) the percentage determined under subsection (b)(2) for the State.

(e) TRANSITION RULES.—

(1) For the fiscal years 1991 through 1993, the amount of an allotment under section 2641 shall be the greater of the

amount determined under subsection (a) and an amount equal to the amount applicable under paragraph (2) for the fiscal year involved.

(2) For purposes of paragraph (1)—

(A) the amount applicable for fiscal year 1991 is an amount equal to the amount received by the State involved from the Secretary, acting through the Director of the Centers for Disease Control and Prevention, for fiscal year 1990 for the provision of counseling and testing services with respect to HIV;

(B) the amount applicable for fiscal year 1992 is 85 percent of the amount specified in subparagraph (A); and

(C) the amount applicable for fiscal year 1993 is 70 percent of the amount specified in subparagraph (A).

SEC. 2649A. [300ff-49a] MISCELLANEOUS PROVISIONS.

The Secretary may not make a grant under section 2641 unless—

(1) the State involved submits to the Secretary a comprehensive plan for the organization and delivery of the early intervention services to be funded with the grant that includes a description of the purposes for which the State intends to use such assistance, including—

(A) the services and activities to be provided and an explanation of the manner in which the elements of the program to be implemented by the State with the grant will maximize the quality of early intervention services available to individuals with HIV disease throughout the State; and

(B) a description of the manner in which services funded with the grant will be coordinated with other available related services for individuals with HIV disease; and

(2) the State agrees that—

(A) the public health agency administering the grant will conduct public hearings regarding the proposed use and distribution of the grant;

(B) to the maximum extent practicable, early intervention services delivered pursuant to the grant will be provided without regard to the ability of the individual to pay for such services and without regard to the current or past health condition of the individual with HIV disease;

(C) early intervention services under the grant will be provided in settings accessible to low-income individuals with HIV disease; and

(D) outreach to low-income individuals with HIV disease will be provided to inform such individuals of the services available pursuant to the grant.

SEC. 2650. [300ff-50] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of making grants under section 2641, there are authorized to be appropriated \$230,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.

Subpart II—Categorical Grants

SEC. 2651. [300ff-51] ESTABLISHMENT OF PROGRAM.

(a) IN GENERAL.—For the purposes described in subsection (b), the Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to public and nonprofit private entities specified in section 2652(a).

(b) PURPOSES OF GRANTS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees to expend the grant for the purposes of providing, on an outpatient basis, each of the early intervention services specified in paragraph (2) with respect to HIV disease.

(2) SPECIFICATION OF EARLY INTERVENTION SERVICES.—The early intervention services referred to in paragraph (1) are—

(A) counseling individuals with respect to HIV disease in accordance with section 2662;

(B) testing individuals with respect to such disease, including tests to confirm the presence of the disease, tests to diagnose the extent of the deficiency in the immune system, and tests to provide information on appropriate therapeutic measures for preventing and treating the deterioration of the immune system and for preventing and treating conditions arising from the disease;

(C) referrals described in paragraph (3);

(D) other clinical and diagnostic services regarding HIV disease, and periodic medical evaluations of individuals with the disease;

(E) providing the therapeutic measures described in subparagraph (B).

(3) REFERRALS.—The services referred to in paragraph (2)(C) are referrals of individuals with HIV disease to appropriate providers of health and support services, including, as appropriate—

(A) to entities receiving amounts under part A or B for the provision of such services;

(B) to biomedical research facility¹ of institutions of higher education that offer experimental treatment for such disease, or to community-based organizations or other entities that provide such treatment; or

(C) to grantees under section 2671, in the case of a pregnant woman.

(4) REQUIREMENT OF AVAILABILITY OF ALL EARLY INTERVENTION SERVICES THROUGH EACH GRANTEE.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that each of the early intervention services specified in paragraph (2) will be available through the grantee. With respect to compliance with such agreement, such a grantee may expend the grant to provide the early intervention services directly, and may expend the grant to enter into agreements with public or nonprofit private entities under which the entities provide the services.

¹ So in original. See Public Law 101-381. Probably should be "facilities".

(5) **OPTIONAL SERVICES.**—A grantee under subsection (a)—

(A) may expend the grant to provide outreach services to individuals who may have HIV disease or may be at risk of the disease, and who may be unaware of the availability and potential benefits of early treatment of the disease, and to provide outreach services to health care professionals who may be unaware of such availability and potential benefits; and

(B) may, in the case of individuals who seek early intervention services from the grantee, expend the grant—

(i) for case management to provide coordination in the provision of health care services to the individuals and to review the extent of utilization of the services by the individuals; and

(ii) to provide assistance to the individuals regarding establishing the eligibility of the individuals for financial assistance and services under Federal, State, or local programs providing for health services, mental health services, social services, or other appropriate services.

(c) **PARTICIPATION IN CERTAIN CONSORTIUM.**—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees to make reasonable efforts to participate in a consortium established with a grant under section 2612(a)(1) regarding comprehensive services to individuals with HIV disease, if such a consortium exist¹ in the geographic area with respect to which the applicant is applying to receive such a grant.

SEC. 2652. [300ff-52] MINIMUM QUALIFICATIONS OF GRANTEEES.

(a) **IN GENERAL.**—The entities referred to in section 2651(a) are public entities and nonprofit private entities that are—

(1) migrant health centers under section 329 or community health centers under section 330;

(2) grantees under section 340 (regarding health services for the homeless);

(3) grantees under section 1001 (regarding family planning) other than States;

(4) comprehensive hemophilia diagnostic and treatment centers;

(5) Federally-qualified health centers under section 1905(1)(2)(B) of the Social Security Act; or

(6) nonprofit private entities that provide comprehensive primary care services to populations at risk of HIV disease.

(b) **STATUS AS MEDICAID PROVIDER.**—

(1) **IN GENERAL.**—Subject to paragraph (2), the Secretary may not make a grant under section 2651 for the provision of services described in subsection (b) of such section in a State unless, in the case of any such service that is available pursuant to the State plan approved under title XIX of the Social Security Act for the State—

(A) the applicant for the grant will provide the service directly, and the applicant has entered into a participation

¹ So in original. See Public Law 101-381. Probably should be "exists".

agreement under the State plan and is qualified to receive payments under such plan; or

(B) the applicant for the grant will enter into an agreement with a public or nonprofit private entity under which the entity will provide the service, and the entity has entered into such a participation agreement and is qualified to receive such payments.

(2) **WAIVER REGARDING CERTAIN SECONDARY AGREEMENTS.—**

(A) In the case of an entity making an agreement pursuant to paragraph (1)(B) regarding the provision of services, the requirement established in such paragraph regarding a participation agreement shall be waived by the Secretary if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(B) A determination by the Secretary of whether an entity referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the entity accepts voluntary donations regarding the provision of services to the public.

SEC. 2653. [300ff-53] PREFERENCES IN MAKING GRANTS.

(a) **IN GENERAL.**—In making grants under section 2651, the Secretary shall give preference to any qualified applicant experiencing an increase in the burden of providing services regarding HIV disease, as indicated by the factors specified in subsection (b).

(b) **SPECIFICATION OF FACTORS.—**

(1) **IN GENERAL.**—In the case of the geographic area with respect to which the entity involved is applying for a grant under section 2651, the factors referred to in subsection (a), as determined for the period specified in paragraph (2), are—

(A) the number of cases of acquired immune deficiency syndrome;

(B) the rate of increase in such cases;

(C) the lack of availability of early intervention services;

(D) the number of other cases of sexually transmitted diseases, and the number of cases of tuberculosis and of drug abuse;

(E) the rate of increase in each of the cases specified in subparagraph (D);

(F) the lack of availability of primary health services from providers other than such applicant; and

(G) the distance between such area and the nearest community that has an adequate level of availability of appropriate HIV-related services, and the length of time required to travel such distance.

(2) **RELEVANT PERIOD OF TIME.**—The period referred to in paragraph (1) is the 2-year period preceding the fiscal year for which the entity involved is applying to receive a grant under section 2651.

(c) **EQUITABLE ALLOCATIONS.**—In providing preferences for purposes of subsection (b), the Secretary shall equitably allocate the preferences among urban and rural areas.

SEC. 2654. [300ff-54] MISCELLANEOUS PROVISIONS.

(a) **SERVICES FOR INDIVIDUALS WITH HEMOPHILIA.**—In making grants under section 2651, the Secretary shall ensure that any such grants made regarding the provision of early intervention services to individuals with hemophilia are made through the network of comprehensive hemophilia diagnostic and treatment centers.

(b) **TECHNICAL ASSISTANCE.**—The Secretary may, directly or through grants or contracts, provide technical assistance to non-profit private entities regarding the process of submitting to the Secretary applications for grants under section 2651, and may provide technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to such section.

SEC. 2655. [300ff-55] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of making grants under section 2651, there are authorized to be appropriated \$75,000,000 for fiscal years 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.

Subpart III—General Provisions

SEC. 2661. [300ff-61] CONFIDENTIALITY AND INFORMED CONSENT.

(a) **CONFIDENTIALITY.**—The Secretary may not make a grant under this part unless—

(1) in the case of any State applying for a grant under section 2641, the State agrees to ensure that information regarding the receipt of early intervention services is maintained confidentially pursuant to law or regulations in a manner not inconsistent with applicable law; and

(2) in the case of any entity applying for a grant under section 2651, the entity agrees to ensure that information regarding the receipt of early intervention services pursuant to the grant is maintained confidentially in a manner not inconsistent with applicable law.

(b) **INFORMED CONSENT.**—

(1) **IN GENERAL.**—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, in testing an individual for HIV disease, the applicant will test an individual only after obtaining from the individual a statement, made in writing and signed by the individual, declaring that the individual has undergone the counseling described in section 2662(a) and that the decision of the individual with respect to undergoing such testing is voluntarily made.

(2) **PROVISIONS REGARDING ANONYMOUS TESTING.**—

(A) If, pursuant to section 2664(b), an individual will undergo testing pursuant to this part through the use of a pseudonym, a grantee under such section shall be considered to be in compliance with the agreement made under paragraph (1) if the individual signs the statement described in such subsection using the pseudonym.

(B) If, pursuant to section 2664(b), an individual will undergo testing pursuant to this part without providing any information relating to the identity of the individual, a grantee under such section shall be considered to be in compliance with the agreement made under paragraph (1) if the individual orally provides the declaration described in such paragraph.

SEC. 2662. [300ff-62] PROVISION OF CERTAIN COUNSELING SERVICES.

(a) **COUNSELING BEFORE TESTING.**—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, before testing an individual for HIV disease, the applicant will provide to the individual appropriate counseling regarding the disease (based on the most recently available scientific data), including counseling on—

(1) measures for the prevention of exposure to, and the transmission of, HIV;

(2) the accuracy and reliability of the results of testing for HIV disease;

(3) the significance of the results of such testing, including the potential for developing acquired immune deficiency syndrome;

(4) encouraging the individual, as appropriate, to undergo such testing;

(5) the benefits of such testing, including the medical benefits of diagnosing HIV disease in the early stages and the medical benefits of receiving early intervention services during such stages;

(6) provisions of law relating to the confidentiality of the process of receiving such services, including information regarding any disclosures that may be authorized under applicable law and information regarding the availability of anonymous counseling and testing pursuant to section 2664(b); and

(7) provisions of applicable law relating to discrimination against individuals with HIV disease.

(b) **COUNSELING OF INDIVIDUALS WITH NEGATIVE TEST RESULTS.**—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, if the results of testing conducted for HIV disease indicate that an individual does not have the disease, the applicant will review for the individual the information provided pursuant to subsection (a), including—

(1) the information described in paragraphs (1) through (3) of such subsection; and

(2) the appropriateness of further counseling, testing, and education of the individual regarding such disease.

(c) **COUNSELING OF INDIVIDUALS WITH POSITIVE TEST RESULTS.**—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, if the results of testing for HIV disease indicate that the individual has the disease, the applicant will provide to the individual appropriate counseling regarding such disease, including—

(1) reviewing the information described in paragraphs (1) through (3) of subsection (a);

(2) reviewing the appropriateness of further counseling, testing, and education of the individual regarding such disease; and

(3) providing counseling on—

(A) the availability, through the applicant, of early intervention services;

(B) the availability in the geographic area of appropriate health care, mental health care, and social and support services, including providing referrals for such services, as appropriate;

(C) the benefits of locating and counseling any individual by whom the infected individual may have been exposed to HIV and any individual whom the infected individual may have exposed to HIV; and

(D) the availability of the services of public health authorities with respect to locating and counseling any individual described in subparagraph (C).

(d) **ADDITIONAL REQUIREMENTS REGARDING APPROPRIATE COUNSELING.**—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, in counseling individuals with respect to HIV disease, the applicant will ensure that the counseling is provided under conditions appropriate to the needs of the individuals.

(e) **COUNSELING OF EMERGENCY RESPONSE EMPLOYEES.**—The Secretary may not make a grant under this part to a State unless the State agrees that, in counseling individuals with respect to HIV disease, the State will ensure that, in the case of emergency response employees, the counseling is provided to such employees under conditions appropriate to the needs of the employees regarding the counseling.

(f) **RULE OF CONSTRUCTION REGARDING COUNSELING WITHOUT TESTING.**—Agreements made pursuant to this section may not be construed to prohibit any grantee under this part from expending the grant for the purpose of providing counseling services described in this section to an individual who does not undergo testing for HIV disease as a result of the grantee or the individual determining that such testing of the individual is not appropriate.

SEC. 2663. [300ff-63] APPLICABILITY OF REQUIREMENTS REGARDING CONFIDENTIALITY, INFORMED CONSENT, AND COUNSELING.

The Secretary may not make a grant under this part unless the applicant for the grant agrees that, with respect to testing for HIV disease, any such testing carried out by the applicant will, without regard to whether such testing is carried out with Federal funds, be carried out in accordance with conditions described in sections 2661 and 2662.

SEC. 2664. [300ff-64] ADDITIONAL REQUIRED AGREEMENTS.

(a) **REPORTS TO SECRETARY.**—The Secretary may not make a grant under this part unless—

(1) the applicant submits to the Secretary—

(A) a specification of the expenditures made by the applicant for early intervention services for the fiscal year

preceding the fiscal year for which the applicant is applying to receive the grant; and

(B) an estimate of the number of individuals to whom the applicant has provided such services for such fiscal year; and

(2) the applicant agrees to submit to the Secretary a report providing—

(A) the number of individuals to whom the applicant provides early intervention services pursuant to the grant;

(B) epidemiological and demographic data on the population of such individuals;

(C) the extent to which the costs of HIV-related health care for such individuals are paid by third-party payors;

(D) the average costs of providing each category of early intervention service; and

(E) the aggregate amounts expended for each such category.

(b) PROVISION OF OPPORTUNITIES FOR ANONYMOUS COUNSELING AND TESTING.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, to the extent permitted under State law, regulation or rule, the applicant will offer substantial opportunities for an individual—

(1) to undergo counseling and testing regarding HIV disease without being required to provide any information relating to the identity of the individual; and

(2) to undergo such counseling and testing through the use of a pseudonym.

(c) PROHIBITION AGAINST REQUIRING TESTING AS CONDITION OF RECEIVING OTHER HEALTH SERVICES.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, with respect to an individual seeking health services from the applicant, the applicant will not require the individual to undergo testing for HIV as a condition of receiving any health services unless such testing is medically indicated in the provision of the health services sought by the individual.

(d) MAINTENANCE OF SUPPORT.—The Secretary may not make a grant under this part unless the applicant for the grant agrees to maintain the expenditures of the applicant for early intervention services at a level equal to not less than the level of such expenditures maintained by the State for the fiscal year preceding the fiscal year for which the applicant is applying to receive the grant.

(e) REQUIREMENTS REGARDING IMPOSITION OF CHARGES FOR SERVICES.—

(1) IN GENERAL.—The Secretary may not make a grant under this part unless, subject to paragraph (5), the applicant for the grant agrees that—

(A) in the case of individuals with an income less than or equal to 100 percent of the official poverty line, the applicant will not impose a charge on any such individual for the provision of early intervention services under the grant;

(B) in the case of individuals with an income greater than 100 percent of the official poverty line, the applicant—

(i) will impose a charge on each such individual for the provision of such services; and

(ii) will impose the charge according to a schedule of charges that is made available to the public.

(2) LIMITATION ON CHARGES REGARDING INDIVIDUALS SUBJECT TO CHARGES.—With respect to the imposition of a charge for purposes of paragraph (1)(B)(ii), the Secretary may not make a grant under this part unless, subject to paragraph (5), the applicant for the grant agrees that—

(A) in the case of individuals with an income greater than 100 percent of the official poverty line and not exceeding 200 percent of such poverty line, the applicant will not, for any calendar year, impose charges in an amount exceeding 5 percent of the annual gross income of the individual involved;

(B) in the case of individuals with an income greater than 200 percent of the official poverty line and not exceeding 300 percent of such poverty line, the applicant will not, for any calendar year, impose charges in an amount exceeding 7 percent of the annual gross income of the individual involved; and

(C) in the case of individuals with an income greater than 300 percent of the official poverty line, the applicant will not, for any calendar year, impose charges in an amount exceeding 10 percent of the annual gross income of the individual involved.

(3) ASSESSMENT OF CHARGE.—With respect to compliance with the agreement made under paragraph (1), a grantee under this part may, in the case of individuals subject to a charge for purposes of such paragraph—

(A) assess the amount of the charge in the discretion of the grantee, including imposing only a nominal charge for the provision of services, subject to the provisions of such paragraph regarding public schedules and of paragraph (2) regarding limitations on the maximum amount of charges; and

(B) take into consideration the medical expenses of individuals in assessing the amount of the charge, subject to such provisions.

(4) APPLICABILITY OF LIMITATION ON AMOUNT OF CHARGE.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that the limitations established in paragraph (2) regarding the imposition of charges for services applies to the annual aggregate of charges imposed for such services, without regard to whether they are characterized as enrollment fees, premiums, deductibles, cost sharing, copayments, coinsurance, or similar charges.

(5) WAIVER REGARDING CERTAIN SECONDARY AGREEMENTS.—The requirement established in paragraph (1)(B)(i) shall be waived by the Secretary in the case of any entity for whom the Secretary has granted a waiver under section 2642(b) or 2652(b)(2).

(f) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—

(1) IN GENERAL.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, subject to paragraph (2), the grant will not be expended by the applicant, or by any entity receiving amounts from the applicant for the provision of early intervention services, to make payment for any such service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such service—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(B) by an entity that provides health services on a pre-paid basis.

(2) APPLICABILITY TO CERTAIN SECONDARY AGREEMENTS FOR PROVISION OF SERVICES.—An agreement made under paragraph (1) shall not apply in the case of an entity through which a grantee under this part provides early intervention services if the Secretary has provided a waiver under section 2642(b) or 2652(b)(2) regarding the entity.

(g) ADMINISTRATION OF GRANT.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that—

(1) the applicant will not expend amounts received pursuant to this part for any purpose other than the purposes described in the subpart under which the grant involved is made;

(2) the applicant will establish such procedures for fiscal control and fund accounting as may be necessary to ensure proper disbursement and accounting with respect to the grant; and

(3) the applicant will not expend more than 5 percent of the grant for administrative expenses with respect to the grant.

(h) CONSTRUCTION.—A State may not use amounts received under a grant awarded under section 2641 to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or to make cash payments to intended recipients of services.

SEC. 2665. [300ff-65] REQUIREMENT OF SUBMISSION OF APPLICATION CONTAINING CERTAIN AGREEMENTS AND ASSURANCES.

The Secretary may not make a grant under this part unless—

(1) an application for the grant is submitted to the Secretary containing agreements and assurances in accordance with this part and containing the information specified in section 2664(a)(1);

(2) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

SEC. 2666. [300ff-66] PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) **IN GENERAL.**—Upon the request of a grantee under this part, the Secretary may, subject to subsection (b), provide supplies, equipment, and services for the purpose of aiding the grantee in providing early intervention services and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(b) **LIMITATION.**—With respect to a request described in subsection (a), the Secretary shall reduce the amount of payments under the grant involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 2667. [300ff-67] USE OF FUNDS.

Counseling programs carried out under this part—

(1) shall not be designed to promote or encourage, directly, intravenous drug abuse or sexual activity, homosexual or heterosexual;

(2) shall be designed to reduce exposure to and transmission of HIV disease by providing accurate information; and

(3) shall provide information on the health risks of promiscuous sexual activity and intravenous drug abuse.

PART D—GENERAL PROVISIONS**SEC. 2671. [300ff-71] DEMONSTRATION GRANTS FOR RESEARCH AND SERVICES FOR PEDIATRIC PATIENTS REGARDING ACQUIRED IMMUNE DEFICIENCY SYNDROME.**

(a) **IN GENERAL.**—The Secretary, acting through the Administrator of the Health Resources and Services Administration and the Director of the National Institutes of Health, shall make demonstration grants to community health centers, and other appropriate public or nonprofit private entities that provide primary health care to the public, for the purpose of—

(1) conducting, at the health facilities of such entities, clinical research on therapies for pediatric patients with HIV disease as well as pregnant women with HIV disease; and

(2) with respect to the pediatric patients who participate in such research, providing health care on an outpatient basis to such patients and the families of such patients.

(b) **MINIMUM QUALIFICATIONS OF GRANTEES.**—The Secretary may not make a grant under subsection (a) unless the health facility operated by the applicant for the grant serves a significant number of pediatric patients and pregnant women with HIV disease.

(c) **COOPERATION WITH BIOMEDICAL INSTITUTIONS.**—

(1) **DESIGN OF RESEARCH PROTOCOL.**—The Secretary may not make a grant under subsection (a) unless the applicant for the grant—

(A) has entered into a cooperative agreement or contract with an appropriately qualified entity with expertise in biomedical research under which the entity will assist

the applicant in designing and conducting a protocol for the research to be conducted pursuant to the grant; and

(B) agrees to provide the clinical data developed in the research to the Director of the National Institutes of Health.

(2) ANALYSIS AND EVALUATION.—The Secretary, acting through the Director of the National Institutes of Health—

(A) may assist grantees under subsection (a) in designing and conducting protocols described in subparagraph (A) of paragraph (1); and

(B) shall analyze and evaluate the data submitted to the Director pursuant to subparagraph (B) of such paragraph.

(d) CASE MANAGEMENT.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees to provide for the case management of the pediatric patient involved and the family of the patient.

(e) REFERRALS FOR ADDITIONAL SERVICES.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees to provide for the pediatric patient involved and the family of the patient—

(1) referrals for inpatient hospital services, treatment for substance abuse, and mental health services; and

(2) referrals for other social and support services, as appropriate.

(f) INCIDENTAL SERVICES.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees to provide the family of the pediatric patient involved with such transportation, child care, and other incidental services as may be necessary to enable the pediatric patient and the family of the patient to participate in the program established by the applicant pursuant to such subsection.

(g) APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(h) EVALUATIONS.—The Secretary shall, directly or through contracts with public and private entities, provide for evaluations of programs carried out pursuant to subsection (a).

(i) DEFINITION.—For purposes of this section, the term “community health center” has the meaning given such term in section 330(a).

(j) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$20,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.

SEC. 2672. [300ff-72] PROVISIONS RELATING TO BLOOD BANKS.

(a) INFORMATIONAL AND TRAINING PROGRAMS.—The Secretary shall—

(1) develop and make available to technical and supervisory personnel employed at blood banks and facilities that

produce blood products, materials and information concerning measures that may be implemented to protect the safety of the blood supply with respect to the activities of such personnel, including—

(A) state-of-the-art diagnostic and testing procedures relating to pathogens in the blood supply; and

(B) quality assurance procedures relating to the safety of the blood supply and of blood products; and

(2) develop and implement a training program that is designed to increase the number of employees of the Department of Health and Human Services who are qualified to conduct inspections of blood banks and facilities that produce blood products.

(b) UPDATES.—The Secretary shall periodically review and update the materials and information made available under informational or training programs conducted under subsection (a).

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, \$1,500,000 for fiscal year 1991, and such sums as may be necessary in each of the fiscal years 1992 through 1995.

SEC. 2673. [300ff-73] RESEARCH, EVALUATION, AND ASSESSMENT PROGRAM.

(a) ESTABLISHMENT.—The Secretary, acting through the Agency for Health Care Policy and Research, shall establish a program to enable independent research to be conducted by individuals and organizations with appropriate expertise in the fields of health, health policy, and economics (particularly health care economics) to develop—

(1) a comparative assessment of the impact and cost-effectiveness of major models for organizing and delivering HIV-related health care, mental health care, early intervention, and support services, that shall include a report concerning patient outcomes, satisfaction, perceived quality of care, and total cumulative cost, and a review of the appropriateness of such models for the delivery of health and support services to infants, children, women, and families with HIV disease;

(2) through a review of private sector financing mechanisms for the delivery of HIV-related health and support services, an assessment of strategies for maintaining private health benefits for individuals with HIV disease and an assessment of specific business practices or regulatory barriers that could serve to reduce access to private sector benefit programs;

(3) an assessment of the manner in which different points-of-entry to the health care system affect the cost, quality, and outcome of the care and treatment of individuals and families with HIV disease; and

(4) a summary report concerning the major and continuing unmet needs in health care, mental health care, early intervention, and support services for individuals and families with HIV disease in urban and rural areas.

(b) REPORT.—Not later than 2 years after the date of enactment of this title, and periodically thereafter, the Secretary shall prepare and submit, to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and

Human Resources of the Senate, a progress report that contains the findings and assessments developed under subsection (a).

(c) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to carry out this section, such sums as may be necessary for each of the fiscal years 1991 through 1995.

SEC. 2674. [300ff-74] EVALUATIONS AND REPORTS.

(a) **EVALUATIONS.**—The Secretary shall, directly or through grants and contracts, evaluate programs carried out under this title.

(b) **REPORT TO CONGRESS.**—The Secretary shall, not later than 1 year after the date on which amounts are first appropriated under this title, and annually thereafter, prepare and submit to the appropriate Committees of Congress a report—

(1) summarizing all of the reports that are required to be submitted to the Secretary under this title;

(2) recommending criteria to be used in determining the geographic areas with the most substantial need for HIV-related health services;

(3) summarizing all of the evaluations carried out pursuant to subsection (a) during the period for which the report under this subsection is prepared; and

(4) making such recommendations for administrative and legislative initiatives with respect to this title as the Secretary determines to be appropriate.

(c) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to carry out this section, such sums as may be necessary for each of the fiscal years 1991 through 1995.

SEC. 2675. [300ff-75] COORDINATION.

(a) **REQUIREMENT.**—The Secretary shall assure that the Health Resources and Services Administration and the Centers for Disease Control and Prevention will coordinate the planning of the funding of programs authorized under this title to assure that health support services for individuals with HIV disease are integrated with each other and that the continuity of care of individuals with HIV disease is enhanced. In coordinating the allocation of funds made available under this title the Health Resources and Services Administration and the Centers for Disease Control and Prevention shall utilize planning information submitted to such agencies by the States and entities eligible for support.

(b) **INTEGRATION BY STATE.**—As a condition of receipt of funds under this title, a State shall assure the Secretary that health support services funded under this title will be integrated with each other, that programs will be coordinated with other available programs (including Medicaid) and that the continuity of care of individuals with HIV disease is enhanced.

(c) **INTEGRATION BY LOCAL OR PRIVATE ENTITIES.**—As a condition of receipt of funds under this title, a local government or private nonprofit entity shall assure the Secretary that services funded under this title will be integrated with each other, that programs will be coordinated with other available programs (including Medicaid) and that the continuity of care of individuals with HIV is enhanced.

SEC. 2676. [300ff-76] DEFINITIONS.

For purposes of this title:

(1) **COUNSELING.**—The term “counseling” means such counseling provided by an individual trained to provide such counseling.

(2) **DESIGNATED OFFICER OF EMERGENCY RESPONSE EMPLOYEES.**—The term “designated officer of emergency response employees” means an individual designated under section 26____¹ by the public health officer of the State involved.

(3) **EMERGENCY.**—The term “emergency” means an emergency involving injury or illness.

(4) **EMERGENCY RESPONSE EMPLOYEE.**—The term “emergency response employees” means firefighters, law enforcement officers, paramedics, emergency medical technicians, and other individuals (including employees of legally organized and recognized volunteer organizations, without regard to whether such employees receive nominal compensation) who, in the course of professional duties, respond to emergencies in the geographic area involved.

(5) **EMPLOYER OF EMERGENCY RESPONSE EMPLOYEES.**—The term “employer of emergency response employees” means an organization that, in the course of professional duties, responds to emergencies in the geographic area involved.

(6) **EXPOSED.**—The term “exposed”, with respect to HIV disease or any other infectious disease, means to be in circumstances in which there is a significant risk of becoming infected with the etiologic agent for the disease involved.

(7) **FAMILIES WITH HIV DISEASE.**—The term “families with HIV disease” means families in which one or more members have HIV disease.

(8) **HIV.**—The term “HIV” means infection with the etiologic agent for acquired immune deficiency syndrome.

(9) **HIV DISEASE.**—The term “HIV disease” means infection with the etiologic agent for acquired immune deficiency syndrome, and includes any condition arising from such syndrome.

(10) **OFFICIAL POVERTY LINE.**—The term “official poverty line” means the poverty line established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(a)² of the Omnibus Budget Reconciliation Act of 1981.

(11) **PERSON.**—The term “person” includes one or more individuals, governments (including the Federal Government and the governments of the States), governmental agencies, political subdivisions, labor unions, partnerships, associations, corporations, legal representatives, mutual companies, joint-stock companies, trusts, unincorporated organizations, receivers, trustees, and trustees in cases under title 11, United States Code.

(12) **STATE.**—The term “State”, except as otherwise specifically provided, means each of the 50 States, the District of Columbia, the Virgin Islands, Guam, American Samoa, the

¹ So in original. See section 401 of Public Law 101-381.

² So in original. See Public Law 101-381. Probably should be “section 673(2)”.

Commonwealth of the Northern Mariana Islands, Puerto Rico, and the Republic of the Marshall Islands.

PART E—EMERGENCY RESPONSE EMPLOYEES

SUBPART I—GUIDELINES AND MODEL CURRICULUM¹

SEC. 2680. [300ff-80] GRANTS FOR IMPLEMENTATION.

(a) IN GENERAL.—With respect to the recommendations contained in the guidelines and the model curriculum developed under section 253 of Public Law 100-607, the Secretary shall make grants to States and political subdivisions of States for the purpose of assisting grantees regarding the initial implementation of such portions of the recommendations as are applicable to emergency response employees.

(b) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$5,000,000 for each of the fiscal years 1991 through 1995.

SUBPART II—NOTIFICATIONS OF POSSIBLE EXPOSURE TO INFECTIOUS DISEASES¹

SEC. 2681. [300ff-81] INFECTIOUS DISEASES AND CIRCUMSTANCES RELEVANT TO NOTIFICATION REQUIREMENTS.

(a) IN GENERAL.—Not later than 180 days after the date of the enactment of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, the Secretary shall complete the development of—

(1) a list of potentially life-threatening infectious diseases to which emergency response employees may be exposed in responding to emergencies;

(2) guidelines describing the circumstances in which such employees may be exposed to such diseases, taking into account the conditions under which emergency response is provided; and

(3) guidelines describing the manner in which medical facilities should make determinations for purposes of section 2683(d).

(b) SPECIFICATION OF AIRBORNE INFECTIOUS DISEASES.—The list developed by the Secretary under subsection (a)(1) shall include a specification of those infectious diseases on the list that are routinely transmitted through airborne or aerosolized means.

(c) DISSEMINATION.—The Secretary shall—

(1) transmit to State public health officers copies of the list and guidelines developed by the Secretary under subsection (a) with the request that the officers disseminate such copies as appropriate throughout the States; and

¹Typeface is so in original. See section 411(a) of Public Law 101-381.

(2) make such copies available to the public.

SEC. 2682. [300ff-82] ROUTINE NOTIFICATIONS WITH RESPECT TO AIRBORNE INFECTIOUS DISEASES IN VICTIMS ASSISTED.

(a) ROUTINE NOTIFICATION OF DESIGNATED OFFICER.—

(1) DETERMINATION BY TREATING FACILITY.—If a victim of an emergency is transported by emergency response employees to a medical facility and the medical facility makes a determination that the victim has an airborne infectious disease, the medical facility shall notify the designated officer of the emergency response employees who transported the victim to the medical facility of the determination.

(2) DETERMINATION BY FACILITY ASCERTAINING CAUSE OF DEATH.—If a victim of an emergency is transported by emergency response employees to a medical facility and the victim dies at or before reaching the medical facility, the medical facility ascertaining the cause of death shall notify the designated officer of the emergency response employees who transported the victim to the initial medical facility of any determination by the medical facility that the victim had an airborne infectious disease.

(b) REQUIREMENT OF PROMPT NOTIFICATION.—With respect to a determination described in paragraph (1) or (2), the notification required in each of such paragraphs shall be made as soon as is practicable, but not later than 48 hours after the determination is made.

SEC. 2683. [300ff-83] REQUEST FOR NOTIFICATIONS WITH RESPECT TO VICTIMS ASSISTED.

(a) INITIATION OF PROCESS BY EMPLOYEE.—If an emergency response employee believes that the employee may have been exposed to an infectious disease by a victim of an emergency who was transported to a medical facility as a result of the emergency, and if the employee attended, treated, assisted, or transported the victim pursuant to the emergency, then the designated officer of the employee shall, upon the request of the employee, carry out the duties described in subsection (b) regarding a determination of whether the employee may have been exposed to an infectious disease by the victim.

(b) INITIAL DETERMINATION BY DESIGNATED OFFICER.—The duties referred to in subsection (a) are that—

(1) the designated officer involved collect the facts relating to the circumstances under which, for purposes of subsection (a), the employee involved may have been exposed to an infectious disease; and

(2) the designated officer evaluate such facts and make a determination of whether, if the victim involved had any infectious disease included on the list issued under paragraph (1) of section 2681(a), the employee would have been exposed to the disease under such facts, as indicated by the guidelines issued under paragraph (2) of such section.

(c) SUBMISSION OF REQUEST TO MEDICAL FACILITY.—

(1) IN GENERAL.—If a designated officer makes a determination under subsection (b)(2) that an emergency response employee may have been exposed to an infectious disease, the

designated officer shall submit to the medical facility to which the victim involved was transported a request for a response under subsection (d) regarding the victim of the emergency involved.

(2) FORM OF REQUEST.—A request under paragraph (1) shall be in writing and be signed by the designated officer involved, and shall contain a statement of the facts collected pursuant to subsection (b)(1).

(d) EVALUATION AND RESPONSE REGARDING REQUEST TO MEDICAL FACILITY.—

(1) IN GENERAL.—If a medical facility receives a request under subsection (c), the medical facility shall evaluate the facts submitted in the request and make a determination of whether, on the basis of the medical information possessed by the facility regarding the victim involved, the emergency response employee was exposed to an infectious disease included on the list issued under paragraph (1) of section 2681(a), as indicated by the guidelines issued under paragraph (2) of such section.

(2) NOTIFICATION OF EXPOSURE.—If a medical facility makes a determination under paragraph (1) that the emergency response employee involved has been exposed to an infectious disease, the medical facility shall, in writing, notify the designated officer who submitted the request under subsection (c) of the determination.

(3) FINDING OF NO EXPOSURE.—If a medical facility makes a determination under paragraph (1) that the emergency response employee involved has not been exposed to an infectious disease, the medical facility shall, in writing, inform the designated officer who submitted the request under subsection (c) of the determination.

(4) INSUFFICIENT INFORMATION.—

(A) If a medical facility finds in evaluating facts for purposes of paragraph (1) that the facts are insufficient to make the determination described in such paragraph, the medical facility shall, in writing, inform the designated officer who submitted the request under subsection (c) of the insufficiency of the facts.

(B)(i) If a medical facility finds in making a determination under paragraph (1) that the facility possesses no information on whether the victim involved has an infectious disease included on the list under section 2681(a), the medical facility shall, in writing, inform the designated officer who submitted the request under subsection (c) of the insufficiency of such medical information.

(ii) If after making a response under clause (i) a medical facility determines that the victim involved has an infectious disease, the medical facility shall make the determination described in paragraph (1) and provide the applicable response specified in this subsection.

(e) TIME FOR MAKING RESPONSE.—After receiving a request under subsection (c) (including any such request resubmitted under subsection (g)(2)), a medical facility shall make the applicable

response specified in subsection (d) as soon as is practicable, but not later than 48 hours after receiving the request.

(f) DEATH OF VICTIM OF EMERGENCY.—

(1) FACILITY ASCERTAINING CAUSE OF DEATH.—If a victim described in subsection (a) dies at or before reaching the medical facility involved, and the medical facility receives a request under subsection (c), the medical facility shall provide a copy of the request to the medical facility ascertaining the cause of death of the victim, if such facility is a different medical facility than the facility that received the original request.

(2) RESPONSIBILITY OF FACILITY.—Upon the receipt of a copy of a request for purposes of paragraph (1), the duties otherwise established in this subpart regarding medical facilities shall apply to the medical facility ascertaining the cause of death of the victim in the same manner and to the same extent as such duties apply to the medical facility originally receiving the request.

(g) ASSISTANCE OF PUBLIC HEALTH OFFICER.—

(1) EVALUATION OF RESPONSE OF MEDICAL FACILITY REGARDING INSUFFICIENT FACTS.—

(A) In the case of a request under subsection (c) to which a medical facility has made the response specified in subsection (d)(4)(A) regarding the insufficiency of facts, the public health officer for the community in which the medical facility is located shall evaluate the request and the response, if the designated officer involved submits such documents to the officer with the request that the officer make such an evaluation.

(B) As soon as is practicable after a public health officer receives a request under paragraph (1), but not later than 48 hours after receipt of the request, the public health officer shall complete the evaluation required in such paragraph and inform the designated officer of the results of the evaluation.

(2) FINDINGS OF EVALUATION.—

(A) If an evaluation under paragraph (1)(A) indicates that the facts provided to the medical facility pursuant to subsection (c) were sufficient for purposes of determinations under subsection (d)(1)—

(i) the public health officer shall, on behalf of the designated officer involved, resubmit the request to the medical facility; and

(ii) the medical facility shall provide to the designated officer the applicable response specified in subsection (d).

(B) If an evaluation under paragraph (1)(A) indicates that the facts provided in the request to the medical facility were insufficient for purposes of determinations specified in subsection (c)—

(i) the public health officer shall provide advice to the designated officer regarding the collection and description of appropriate facts; and

(ii) if sufficient facts are obtained by the designated officer—

(I) the public health officer shall, on behalf of the designated officer involved, resubmit the request to the medical facility; and

(II) the medical facility shall provide to the designated officer the appropriate response under subsection (c).

SEC. 2684. [300ff-84] PROCEDURES FOR NOTIFICATION OF EXPOSURE.

(a) **CONTENTS OF NOTIFICATION TO OFFICER.**—In making a notification required under section 2682 or section 2683(d)(2), a medical facility shall provide—

(1) the name of the infectious disease involved; and

(2) the date on which the victim of the emergency involved was transported by emergency response employees to the medical facility involved.

(b) **MANNER OF NOTIFICATION.**—If a notification under section 2682 or section 2682(d)(2)¹ is mailed or otherwise indirectly made—

(1) the medical facility sending the notification shall, upon sending the notification, inform the designated officer to whom the notification is sent of the fact that the notification has been sent; and

(2) such designated officer shall, not later than 10 days after being informed by the medical facility that the notification has been sent, inform such medical facility whether the designated officer has received the notification.

SEC. 2685. [300ff-85] NOTIFICATION OF EMPLOYEE.

(a) **IN GENERAL.**—After receiving a notification for purposes of section 2682 or 2683(d)(2), a designated officer of emergency response employees shall, to the extent practicable, immediately notify each of such employees who—

(1) responded to the emergency involved; and

(2) as indicated by guidelines developed by the Secretary, may have been exposed to an infectious disease.

(b) **CERTAIN CONTENTS OF NOTIFICATION TO EMPLOYEE.**—A notification under this subsection to an emergency response employee shall inform the employee of—

(1) the fact that the employee may have been exposed to an infectious disease and the name of the disease involved;

(2) any action by the employee that, as indicated by guidelines developed by the Secretary, is medically appropriate; and

(3) if medically appropriate under such criteria, the date of such emergency.

(c) **RESPONSES OTHER THAN NOTIFICATION OF EXPOSURE.**—After receiving a response under paragraph (3) or (4) of subsection (d) of section 2683, or a response under subsection (g)(1) of such section, the designated officer for the employee shall, to the extent practicable, immediately inform the employee of the response.

SEC. 2686. [300ff-86] SELECTION OF DESIGNATED OFFICERS.

(a) **IN GENERAL.**—For the purposes of receiving notifications and responses and making requests under this subpart on behalf

¹So in original. See Public Law 101-381. Probably should be "section 2683(d)(2)". Compare with subsection (a) and with section 2685(a).

of emergency response employees, the public health officer of each State shall designate 1 official or officer of each employer of emergency response employees in the State.

(b) PREFERENCE IN MAKING DESIGNATIONS.—In making the designations required in subsection (a), a public health officer shall give preference to individuals who are trained in the provision of health care or in the control of infectious diseases.

SEC. 2687. [300ff-87] LIMITATIONS WITH RESPECT TO DUTIES OF MEDICAL FACILITIES.

The duties established in this subpart for a medical facility—

(1) shall apply only to medical information possessed by the facility during the period in which the facility is treating the victim for conditions arising from the emergency, or during the 60-day period beginning on the date on which the victim is transported by emergency response employees to the facility, whichever period expires first; and

(2) shall not apply to any extent after the expiration of the 30-day period beginning on the expiration of the applicable period referred to in paragraph (1), except that such duties shall apply with respect to any request under section 2683(c) received by a medical facility before the expiration of such 30-day period.

SEC. 2688. [300ff-88] RULES OF CONSTRUCTION.

(a) LIABILITY OF MEDICAL FACILITIES AND DESIGNATED OFFICERS.—This subpart may not be construed to authorize any cause of action for damages or any civil penalty against any medical facility, or any designated officer, for failure to comply with the duties established in this subpart.

(b) TESTING.—This subpart may not, with respect to victims of emergencies, be construed to authorize or require a medical facility to test any such victim for any infectious disease.

(c) CONFIDENTIALITY.—This subpart may not be construed to authorize or require any medical facility, any designated officer of emergency response employees, or any such employee, to disclose identifying information with respect to a victim of an emergency or with respect to an emergency response employee.

(d) FAILURE TO PROVIDE EMERGENCY SERVICES.—This subpart may not be construed to authorize any emergency response employee to fail to respond, or to deny services, to any victim of an emergency.

SEC. 2689. [300ff-89] INJUNCTIONS REGARDING VIOLATION OF PROHIBITION.

(a) IN GENERAL.—The Secretary may, in any court of competent jurisdiction, commence a civil action for the purpose of obtaining temporary or permanent injunctive relief with respect to any violation of this subpart.

(b) FACILITATION OF INFORMATION ON VIOLATIONS.—The Secretary shall establish an administrative process for encouraging emergency response employees to provide information to the Secretary regarding violations of this subpart. As appropriate, the Secretary shall investigate alleged such violations and seek appropriate injunctive relief.

SEC. 2690. [300ff-90] APPLICABILITY OF SUBPART.

This subpart shall not apply in a State if the chief executive officer of the State certifies to the Secretary that the law of the State is in substantial compliance with this subpart.



**DEVELOPMENTAL DISABILITIES ASSISTANCE AND BILL
OF RIGHTS ACT**

DEVELOPMENTAL DISABILITIES ASSISTANCE AND BILL OF RIGHTS ACT

(References in black brackets [] are to title 42, United States Code)

TITLE I—PROGRAMS FOR INDIVIDUALS WITH DEVELOPMENTAL DISABILITIES¹

PART A—GENERAL PROVISIONS

SEC. 100. [6000 Note] SHORT TITLE.

²This title may be cited as the "Developmental Disabilities Assistance and Bill of Rights Act".

SEC. 101. [6000] FINDINGS, PURPOSES, AND POLICY.

(a) FINDINGS.—The Congress finds that—

(1) in 1993 there are more than 3,000,000 individuals with developmental disabilities in the United States;

(2) disability is a natural part of the human experience that does not diminish the right of individuals with developmental disabilities to enjoy the opportunity to live independently, enjoy self-determination, make choices, contribute to society, and experience full integration and inclusion in the economic, political, social, cultural, and educational mainstream of American society;

(3) individuals with developmental disabilities continually encounter various forms of discrimination in critical areas;

(4) there is a lack of public awareness of the capabilities and competencies of individuals with developmental disabilities;

(5) individuals whose disabilities occur during their developmental period frequently have severe disabilities that are likely to continue indefinitely;

(6) individuals with developmental disabilities often require lifelong specialized services and assistance, provided in a coordinated and culturally competent manner by many agencies, professionals, advocates, community representatives, and others to eliminate barriers and to meet the needs of such individuals and their families;

(7) a substantial portion of individuals with developmental disabilities and their families do not have access to appropriate support and services from generic and specialized service systems and remain unserved or underserved;

¹Title I of Public Law 88-164, the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963. (Such title was added by section 2 of Public Law 98-527.)

²The superfluous period is so in law. See section 101(c)(1) of Public Law 103-230 (108 Stat. 285).

(8) family members, friends, and members of the community can play an important role in enhancing the lives of individuals with developmental disabilities, especially when the family and community are provided with the necessary services and supports;

(9) there is a need to ensure that services, supports, and other assistance are provided in a culturally competent manner, that individuals from racial and ethnic minority backgrounds are fully included in all activities under this Act, and that greater efforts are made to recruit individuals from minority backgrounds into the field of developmental disabilities; and

(10) the goals of the Nation properly include the goal of providing individuals with developmental disabilities with the opportunities and support to—

(A) make informed choices and decisions;

(B) live in homes and communities in which such individuals can exercise their full rights and responsibilities as citizens;

(C) pursue meaningful and productive lives;

(D) contribute to their family, community, State, and Nation;

(E) have interdependent friendships and relationships with others; and

(F) achieve full integration and inclusion in society, in an individualized manner, consistent with unique strengths, resources, priorities, concerns, abilities, and capabilities of each individual.

(b) PURPOSE.—The purpose of this Act is to assure that individuals with developmental disabilities and their families participate in the design of and have access to culturally competent services, supports, and other assistance and opportunities that promote independence, productivity, and integration and inclusion into the community, through—

(1) support to State Developmental Disabilities Councils in each State to promote, through systemic change, capacity building, and advocacy activities that are consistent with the policy under subsection (c)(2), a consumer and family-centered, comprehensive system, and a coordinated array of services, supports, and other assistance for individuals with developmental disabilities and their families;

(2) support to protection and advocacy systems in each State to protect the legal and human rights of individuals with developmental disabilities;

(3) support to university affiliated programs to provide interdisciplinary preservice preparation of students and fellows, community service activities, and the dissemination of information and research findings; and

(4) support to national initiatives to collect necessary data, provide technical assistance to State Developmental Disabilities Councils, protection and advocacy systems and university affiliated programs, and support other nationally significant activities.

(c) **POLICY.**—It is the policy of the United States that all programs, projects, and activities receiving assistance under this Act shall be carried out in a manner consistent with the principles that—

(1) individuals with developmental disabilities, including those with the most severe developmental disabilities, are capable of achieving independence, productivity, and integration and inclusion into the community, and often require the provision of services, supports and other assistance to achieve independence, productivity, and integration and inclusion;

(2) individuals with developmental disabilities and their families have competencies, capabilities and personal goals that should be recognized, supported, and encouraged, and any assistance to such individuals should be provided in an individualized manner, consistent with the unique strengths, resources, priorities, concerns, abilities, and capabilities of such individuals;

(3) individuals with developmental disabilities and their families are the primary decisionmakers regarding the services and supports such individuals and their families receive and play decisionmaking roles in policies and programs that affect the lives of such individuals and their families;

(4) services, supports, and other assistance are provided in a manner that demonstrates respect for individual dignity, personal preferences, and cultural differences;

(5) specific efforts must be made to ensure that individuals from racial and ethnic minority backgrounds enjoy effective and meaningful opportunities for full participation in the developmental disabilities service system;

(6) recruitment efforts within developmental disabilities at the level of preservice training, community training, practice, administration and policymaking must focus on bringing larger numbers of racial and ethnic minorities into the field in order to provide appropriate skills, knowledge, role models, and sufficient manpower to address the growing needs of an increasingly diverse population;

(7) with education and support, communities can be responsive to the needs of individuals with developmental disabilities and their families and are enriched by the full and active participation and the contributions by individuals with developmental disabilities and their families; and

(8) individuals with developmental disabilities should have access to opportunities and the necessary support to be included in community life, have interdependent relationships, live in homes and communities, and make contributions to their families, community, State, and Nation.

SEC. 102. [6001] DEFINITIONS.

For purposes of this title:

(1) **AMERICAN INDIAN CONSORTIUM.**—The term “American Indian Consortium” means any confederation of two or more recognized American Indian tribes, created through the official action of each participating tribe, that has a combined total

resident population of 150,000 enrolled tribal members and a contiguous territory of Indian lands in two or more States.

(2) **ASSISTIVE TECHNOLOGY DEVICE.**—The term “assistive technology device” means any item, piece of equipment, or product system, whether acquired commercially, modified or customized, that is used to increase, maintain, or improve functional capabilities of individuals with developmental disabilities.

(3) **ASSISTIVE TECHNOLOGY SERVICE.**—The term “assistive technology service” means any service that directly assists an individual with a developmental disability in the selection, acquisition, or use, of an assistive technology device. Such term includes—

(A) the evaluation of the needs of an individual with a developmental disability, including a functional evaluation of the individual in the individual’s customary environment;

(B) purchasing, leasing, or otherwise providing for the acquisition of assistive technology devices by an individual with a developmental disability;

(C) selecting, designing, fitting, customizing, adapting, applying, maintaining, repairing or replacing assistive technology devices;

(D) coordinating and using other therapies, interventions, or services with assistive technology devices, such as those associated with existing education and rehabilitation plans and programs;

(E) training or technical assistance for an individual with a developmental disability, or, where appropriate, a family member, guardian, advocate, or authorized representative of an individual with a developmental disability; and

(F) training or technical assistance for professionals (including individuals providing education and rehabilitation services), employers, or other individuals who provide services to, employ, or are otherwise substantially involved in the major life functions of, an individual with developmental disabilities.

(4) **CHILD DEVELOPMENT ACTIVITIES.**—The term “child development activities” means such priority area activities as will assist in the prevention, identification, and alleviation of developmental disabilities in children, including early intervention services.

(5) **COMMUNITY LIVING ACTIVITIES.**—The term “community living activities” means such priority area activities as will assist individuals with developmental disabilities to obtain and receive the supports needed to live in their family home or a home of their own with individuals of their choice and to develop supports in the community.

(6) **COMMUNITY SUPPORTS.**—The term “community supports” means activities, services, supports, and other assistance designed to—

(A) assist neighborhoods and communities to be more responsive to the needs of individuals with developmental disabilities and their families;

(B) develop local networks that can provide informal support; and

(C) make communities accessible and enable communities to offer their resources and opportunities to individuals with developmental disabilities and their families.

Such term includes community education, personal assistance services, vehicular and home modifications, support at work, and transportation.

(7) **CULTURALLY COMPETENT.**—The term “culturally competent” means services, supports or other assistance that are conducted or provided in a manner that is responsive to the beliefs, interpersonal styles, attitudes, language and behaviors of individuals who are receiving services, and in a manner that has the greatest likelihood of ensuring their maximum participation in the program.

(8) **DEVELOPMENTAL DISABILITY.**—The term “developmental disability” means a severe, chronic disability of an individual 5 years of age or older that—

(A) is attributable to a mental or physical impairment or combination of mental and physical impairments;

(B) is manifested before the individual attains age 22;

(C) is likely to continue indefinitely;

(D) results in substantial functional limitations in three or more of the following areas of major life activity—

(i) self-care;

(ii) receptive and expressive language;

(iii) learning;

(iv) mobility;

(v) self-direction;

(vi) capacity for independent living; and

(vii) economic self-sufficiency; and

(E) reflects the individual’s need for a combination and sequence of special, interdisciplinary, or generic services, supports, or other assistance that is of lifelong or extended duration and is individually planned and coordinated, except that such term, when applied to infants and young children means individuals from birth to age 5, inclusive, who have substantial developmental delay or specific congenital or acquired conditions with a high probability of resulting in developmental disabilities if services are not provided.

(9) **EARLY INTERVENTION SERVICES.**—The term “early intervention services” means services provided to infants, toddlers, young children, and their families to—

(A) enhance the development of infants, toddlers, and young children with disabilities and to minimize their potential for developmental delay; and

(B) enhance the capacity of families to meet the special needs of their infants, toddlers, and young children.

(10) **EMPLOYMENT ACTIVITIES.**—The term “employment activities” means such priority area activities as will increase the independence, productivity, and integration and inclusion into

the community of individuals with developmental disabilities in work settings.

(11) **FAMILY SUPPORT SERVICE.**—The term “family support service” means services, supports, and other assistance provided to families with members with developmental disabilities that are designed to—

- (A) strengthen the family’s role as primary caregiver;
- (B) prevent inappropriate out-of-the-home placement and maintain family unity; and
- (C) reunite families with members who have been placed out of the home, whenever possible.

Such term includes respite care, rehabilitation technology, personal assistance services, parent training and counseling, support for elderly parents, vehicular and home modifications, and assistance with extraordinary expenses associated with the needs of individuals with developmental disabilities.

(12) **FEDERAL PRIORITY AREAS.**—The term “Federal priority areas” means community living activities, employment activities, child development activities, and system coordination and community education activities.

(13) **INDEPENDENCE.**—The term “independence” means the extent to which individuals with developmental disabilities exert control and choice over their own lives.

(14) **INDIVIDUAL SUPPORTS.**—The term “individual supports” means services, supports, and other assistance that enable an individual with a developmental disability to be independent, productive, integrated, and included into such individual’s community, and that are designed to—

- (A) enable such individual to control such individual’s environment, permitting the most independent life possible;
- (B) prevent placement into a more restrictive living arrangement than is necessary; and
- (C) enable such individual to live, learn, work, and enjoy life in the community.

Such term includes personal assistance services, rehabilitation technology, vehicular and home modifications, support at work, and transportation.

(15) **INTEGRATION AND INCLUSION.**—The term “integration and inclusion”, with respect to individuals with developmental disabilities, means—

- (A) the use by individuals with developmental disabilities of the same community resources that are used by and available to other citizens;
- (B) living in homes close to community resources, with regular contact with citizens without disabilities in their communities;
- (C) the full and active participation by individuals with developmental disabilities in the same community activities and types of employment as citizens without disabilities, and utilization of the same community resources as citizens without disabilities, living, learning, working, and enjoying life in regular contact with citizens without disabilities; and

(D) having friendships and relationships with individuals and families of their own choosing.

(16) NONPROFIT.—The term “nonprofit” means an agency, institution, or organization that is owned or operated by one or more corporations or associations, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(17) OTHER ORGANIZATIONS.—The term “other organizations” means those organizations that are not State agencies or nonprofit agencies, except such organizations may be consulting firms, independent proprietary businesses and providers, and local community groups not organizationally incorporated, and that are interested in supporting individuals with developmental disabilities.

(18) PERSONAL ASSISTANCE SERVICES.—The term “personal assistance services” means a range of services, provided by one or more individuals, designed to assist an individual with a disability to perform daily living activities on or off a job that such individual would typically perform if such individual did not have a disability. Such services shall be designed to increase such individual’s control in life and ability to perform everyday activities on or off such job.

(19) PREVENTION.—The term “prevention” means activities that address the causes of developmental disabilities and the exacerbation of functional limitations, such as activities that—

(A) eliminate or reduce the factors that cause or predispose individuals to developmental disabilities or that increase the prevalence of developmental disabilities;

(B) increase the early identification of existing problems to eliminate circumstances that create or increase functional limitations; and

(C) mitigate against the effects of developmental disabilities throughout the individual’s lifespan.

(20) PRODUCTIVITY.—The term “productivity” means—

(A) engagement in income-producing work that is measured by increased income, improved employment status, or job advancement; or

(B) engagement in work that contributes to a household or community.

(21) PROTECTION AND ADVOCACY SYSTEM.—The term “protection and advocacy system” means a protection and advocacy system established in accordance with section 142.

(22) REHABILITATION TECHNOLOGY.—The term “rehabilitation technology” means the systematic application of technologies, engineering methodologies, or scientific principles to meet the needs of, and address the barriers confronted by, individuals with developmental disabilities in areas that include education, rehabilitation, employment, transportation, independent living, and recreation. Such term includes rehabilitation engineering, assistive technology devices, and assistive technology services.

(23) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

(24) **SERVICE COORDINATION ACTIVITIES.**—The term “service coordination activities” (also referred to as “case management activities”) means activities that assist and enable individuals with developmental disabilities and their families to access services, supports and other assistance, and includes—

(A) the provision of information to individuals with developmental disabilities and their families about the availability of services, supports, and other assistance;

(B) assistance in obtaining appropriate services, supports, and other assistance, which may include facilitating and organizing such assistance;

(C) coordination and monitoring of services, supports, and other assistance provided singly or in combination to individuals with developmental disabilities and their families to ensure accessibility, continuity, and accountability of such assistance; and

(D) follow-along services that ensure, through a continuing relationship, that the changing needs of individuals with developmental disabilities and their families are recognized and appropriately met.

(25) **STATE.**—The term “State”, except as provided in section 155, includes, in addition to each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Republic of Palau (until the Compact of Free Association with Palau takes effect).

(26) **STATE DEVELOPMENTAL DISABILITIES COUNCIL.**—The term “State Developmental Disabilities Council” means a Council established under section 124.

(27) **STATE PRIORITY AREA.**—The term “State priority area” means priority area activities in an area considered essential by the State Developmental Disabilities Council.

(28) **SUPPORTED EMPLOYMENT.**—The term “supported employment” means competitive work in integrated work settings for individuals with developmental disabilities—

(A)(i) for whom competitive employment has not traditionally occurred; or

(ii) for whom competitive employment has been interrupted or intermittent as a result of a severe disability; and

(B) who, because of the nature and severity of their disability, need intensive supported employment services or extended services in order to perform such work.

(29) **SYSTEM COORDINATION AND COMMUNITY EDUCATION ACTIVITIES.**—The term “system coordination and community education activities” means activities that—

(A) eliminate barriers to access and eligibility for services, supports, and other assistance;

(B) enhance systems design, redesign, and integration, including the encouragement of the creation of local service coordination and information and referral statewide systems;

(C) enhance individual, family, and citizen participation and involvement; and

(D) develop and support coalitions and individuals through training in self-advocacy, educating policymakers, and citizen leadership skills.

(30) UNIVERSITY AFFILIATED PROGRAM.—The term “university affiliated program” means a university affiliated program established under section 152.

(31) UNSERVED AND UNDERSERVED.—The term “unserved and underserved” includes populations such as individuals from racial and ethnic minority backgrounds, disadvantaged individuals, individuals with limited-English proficiency, individuals from underserved geographic areas (rural or urban), and specific groups of individuals within the population of individuals with developmental disabilities, including individuals with developmental disabilities attributable to physical impairment, mental impairment, or a combination of physical and mental impairments.

SEC. 104.¹ [6003] RECORDS AND AUDITS.

(a) RECORDS.—Each recipient of assistance under this title shall keep such records as the Secretary shall prescribe;² including—

(1) records which fully disclose—

(A) the amount and disposition by such recipient of the proceeds of such assistance;

(B) the total cost of the project or undertaking in connection with which such assistance is given or used; and

(C) the amount of that portion of the cost of the project or undertaking supplied by other sources; and

(2) such other records as will facilitate an effective audit.

(b) ACCESS.—The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients of assistance under this title that are pertinent to such assistance.

SEC. 106.¹ [6005] STATE CONTROL OF OPERATIONS.

Except as otherwise specifically provided, nothing in this title shall be construed as conferring on any Federal officer or employee the right to exercise any supervision or control over the administration, personnel, maintenance, or operation of any programs, services, and supports for individuals with developmental disabilities with respect to which any funds have been or may be expended under this title.

SEC. 107. [6006] REPORTS.

(a) DEVELOPMENTAL DISABILITIES COUNCIL REPORTS.—By January 1 of each year, each State Developmental Disabilities Council shall prepare and transmit to the Secretary a report of activities carried out during the preceding fiscal year with funds paid to the

¹Sections 103 and 105 were repealed by sections 104 and 106, respectively, of Public Law 103-230 (108 Stat. 293).

²The semicolon is so in law. See section 105(b)(1)(F) of Public Law 103-230 (108 Stat. 293).

State under part B for such fiscal year. Each report shall be in a form prescribed by the Secretary by regulation and shall contain—

(1) a description of activities and accomplishments;

(2) a comparison of accomplishments with the goals, objectives, and proposed activities specified in the State plan submitted under section 122 for such fiscal year;

(3) an accounting of the manner in which funds paid to a State under part B for a fiscal year were expended;

(4) a description of the State Developmental Disabilities Council's response to significant actions taken by the State with respect to any intermediate care facility for the mentally retarded in such State, and with respect to annual survey reports prepared pursuant to section 1902(a)(31) of the Social Security Act and correction or reduction plans prepared pursuant to section 1922 of such Act;

(5) a description of—

(A) the trends and progress made in the State concerning systemic change (including policy reform), capacity building, advocacy, and other actions on behalf of individuals with developmental disabilities, with attention to individuals who are traditionally unserved and underserved, particularly individuals who are members of ethnic and racial minority groups, and individuals from underserved geographic areas;

(B) systemic change, capacity building, and advocacy activities that affect individuals with disabilities other than developmental disabilities; and

(C) a summary of actions taken to improve access and services for unserved and underserved groups;

(6) a description of resources leveraged by activities directly attributable to State Developmental Disabilities Council actions; and

(7) a description of the method by which the State Developmental Disabilities Council shall widely disseminate the annual report to affected constituencies as well as the general public and to assure that the report is available in accessible formats.

(b) **PROTECTION AND ADVOCACY SYSTEM REPORTS.**—By January 1 of each year, each protection and advocacy system established in a State pursuant to part C shall prepare and transmit to the Secretary a report which describes the activities, accomplishments, and expenditures of the system during the preceding fiscal year, including a description of the system's priorities for such fiscal year, the process used to obtain public input, the nature of such input, and how such input was used.

(c) **SECRETARY REPORTS.**—

(1) **IN GENERAL.**—By July 1 of each year the Secretary shall prepare and transmit to the President, the Congress, and the National Council on Disability a report which describes—

(A) the activities and accomplishments of programs supported under parts B, C, D, and E of this title;

(B) the progress made in States in improving the independence, productivity, and integration and inclusion into the community of individuals with developmental disabili-

ities and any activities or services needed to improve such independence, productivity, and integration and inclusion;

(C)(i) the trends and progress made in the States concerning systemic change (including policy reform), capacity building, advocacy, and other actions on behalf of individuals with developmental disabilities, with attention to individuals who are traditionally unserved and underserved, particularly individuals who are members of ethnic and racial minority groups, and individuals from underserved geographic areas;

(ii) systemic change, capacity building, and advocacy activities that affect individuals with disabilities other than developmental disabilities; and

(iii) a summary of actions taken to improve access and services for unserved and underserved groups;

(D) the significant Federal policies that impact on the ability of States to address the needs of individuals with developmental disabilities attributable to physical impairments, mental impairments, or a combination of mental and physical impairments; and

(E) the number of meetings held by the interagency committee established under section 108(b) during the period for which the report is made, which agencies were represented at each such meeting, and the accomplishments of the interagency committee in comparison to the goals and objectives of such committee.

(2) INCLUSION OF COUNCIL AND SYSTEM INFORMATION.—In preparing the report required by this subsection, the Secretary shall include and analyze information submitted in the reports required under subsections (a) and (b) of this section.

SEC. 108. [6007] RESPONSIBILITIES OF THE SECRETARY.

(a) REGULATIONS.—The Secretary, not later than one hundred eighty days after the date of enactment of any Act amending the provisions of this title, shall promulgate such regulations as may be required for the implementation of such amendments.

(b) INTERAGENCY COMMITTEE.—Within 90 days after the date of enactment of the Developmental Disabilities Act of 1984, the Secretary of Health and Human Services and the Secretary of Education shall establish an interagency committee composed of representatives of the Administration on Developmental Disabilities, the Administration on Children, Youth and Families, the Administration on Aging, and the Health Resources and Services Administration, of the Department of Health and Human Services, the Office of Special Education and Rehabilitative Services of the Department of Education, the Department of Labor, and such other Federal departments and agencies as the Secretary of Health and Human Services and the Secretary of Education consider appropriate. Such interagency committee shall meet regularly to coordinate and plan activities conducted by Federal departments and agencies for persons with developmental disabilities. Each meeting of the interagency committee (except for any meetings of any subcommittees of the committee) shall be open to the public. Notice of each meeting, and a statement of the agenda for the meeting, shall

be published in the Federal Register not later than 14 days before the date on which the meeting is to occur.

SEC. 109. [6008] EMPLOYMENT OF INDIVIDUALS WITH DISABILITIES.

As a condition of providing assistance under this title, the Secretary shall require that each recipient of such assistance take affirmative action to employ and advance in employment qualified individuals with disabilities on the same terms and conditions required with respect to the employment of such individuals by the provisions of the Rehabilitation Act of 1973 that govern employment—

- (1) by State rehabilitation agencies and community rehabilitation programs; and
- (2) under Federal contracts and subcontracts.

SEC. 110. [6009] RIGHTS OF INDIVIDUALS WITH DEVELOPMENTAL DISABILITIES.

Congress makes the following findings respecting the rights of individuals with developmental disabilities:

(1) Individuals with developmental disabilities have a right to appropriate treatment, services, and habilitation for such disabilities.

(2) The treatment, services, and habilitation for an individual with developmental disabilities should be designed to maximize the developmental potential of the individual and should be provided in the setting that is least restrictive of the individual's personal liberty.

(3) The Federal Government and the States both have an obligation to assure that public funds are not provided to any institutional or other residential program for individuals with developmental disabilities that—

(A) does not provide treatment, services, and habilitation which is appropriate to the needs of such individuals; or

(B) does not meet the following minimum standards:

(i) Provision of a nourishing, well-balanced daily diet to the individuals with developmental disabilities being served by the program.

(ii) Provision to such individuals of appropriate and sufficient medical and dental services.

(iii) Prohibition of the use of physical restraint on such individuals unless absolutely necessary and prohibition of the use of such restraint as a punishment or as a substitute for a habilitation program.

(iv) Prohibition on the excessive use of chemical restraints on such individuals and the use of such restraints as punishment or as a substitute for a habilitation program or in quantities that interfere with services, treatment, or habilitation for such individuals.

(v) Permission for close relatives of such individuals to visit them at reasonable hours without prior notice.

(vi) Compliance with adequate fire and safety standards as may be promulgated by the Secretary.

(4) All programs for individuals with developmental disabilities should meet standards which are designed to assure the most favorable possible outcome for those served, and—

(A) in the case of residential programs serving individuals in need of comprehensive health-related, habilitative, or rehabilitative services, which are at least equivalent to those standards applicable to intermediate care facilities for the mentally retarded promulgated in regulations of the Secretary on June 3, 1988, as appropriate when taking into account the size of the institutions and the service delivery arrangements of the facilities of the programs;

(B) in the case of other residential programs for individuals with developmental disabilities, which assure that care is appropriate to the needs of the individuals being served by such programs, assure that the individuals admitted to facilities of such programs are individuals whose needs can be met through services provided by such facilities, and assure that the facilities under such programs provide for the humane care of the residents of the facilities, are sanitary, and protect their rights; and

(C) in the case of nonresidential programs, which assure the care provided by such programs is appropriate to the individuals served by the programs.

The rights of individuals with developmental disabilities described in findings made in this section are in addition to any constitutional or other rights otherwise afforded to all individuals.

PART B—FEDERAL ASSISTANCE TO STATE DEVELOPMENTAL DISABILITIES COUNCILS

SEC. 121. [6021] PURPOSE.

The purpose of this part is to provide for allotments to support State Developmental Disabilities Councils in each State to promote, through systemic change, capacity building, and advocacy activities that are consistent with the policy under section 101(c)(2), the development of a consumer and family-centered, comprehensive system and a coordinated array of culturally competent services, supports, and other assistance designed to achieve independence, productivity, and integration and inclusion into the community for individuals with developmental disabilities.

SEC. 122. [6022] STATE PLAN.

(a) **IN GENERAL.**—Any State desiring to take advantage of this part shall have a State plan submitted to, and approved by, the Secretary under this section.

(b) **PLANNING CYCLE.**—The plan under subsection (a) shall be reviewed annually and revised at least once every 3 years.

(c) **STATE PLAN REQUIREMENTS.**—In order to be approved by the Secretary under this section, a State plan shall meet the requirements in paragraphs (1) through (5).

(1) **STATE COUNCIL.**—The plan shall provide for the establishment and maintenance of a State Developmental Disabilities Council in accordance with section 124 and describe the membership of such Council.

(2) DESIGNATED STATE AGENCY.—The plan shall identify the agency or office within the State designated to support the State Developmental Disabilities Council in accordance with this section and section 124(d).

(3) COMPREHENSIVE REVIEW AND ANALYSIS.—The plan shall contain a comprehensive review and analysis of the extent to which services and supports are available to, and the need for services and supports for, individuals with developmental disabilities and their families. Such review and analysis shall include—

(A) a description of the services, supports and other assistance being provided to, or to be provided to, individuals with developmental disabilities and their families under other federally assisted State programs, plans, and policies that the State conducts and in which individuals with developmental disabilities are or may be eligible to participate, including programs relating to education, job training, vocational rehabilitation, public assistance, medical assistance, social services, child welfare, maternal and child health, aging, programs for children with special health care needs, children's mental health, housing, transportation, technology, comprehensive health and mental health, and such other programs as the Secretary may specify;

(B) a description of the extent to which agencies operating such other federally assisted State programs pursue interagency initiatives to improve and enhance services, supports, and other assistance for individuals with developmental disabilities; and

(C) an examination of the provision, and the need for the provision, in the State of the four Federal priority areas and an optional State priority area, including—

(i) an analysis of such Federal and State priority areas in relation to the degree of support for individuals with developmental disabilities attributable to either physical impairment, mental impairment, or a combination of physical and mental impairments;

(ii) an analysis of criteria for eligibility for services, including specialized services and special adaptation of generic services provided by agencies within the State, that may exclude individuals with developmental disabilities from receiving such services;

(iii) an analysis of the barriers that impede full participation of members of unserved and underserved groups;

(iv) consideration of the report conducted pursuant to section 124(e);

(v) consideration of the data collected by the State educational agency under section 618 of the Individuals with Disabilities Education Act;

(vi) an analysis of services, assistive technology, or knowledge that may be unavailable to assist individuals with developmental disabilities;

(vii) an analysis of existing and projected fiscal resources;

(viii) an analysis of any other issues identified by the State Developmental Disabilities Council; and

(ix) the formulation of objectives in systemic change, capacity building, and advocacy to address the issues described in clauses (i) through (vi) for all subpopulations of individuals with developmental disabilities that may be identified by the State Developmental Disabilities Council.

(4) **PLAN OBJECTIVES.**—The plan shall—

(A) specify employment, and at the discretion of the State, any or all of the three other Federal priority areas and an optional State priority area that are selected by the State Developmental Disabilities Council for such Council's major systemic change, capacity building, and advocacy activities to be addressed during the plan period and describe the extent and scope of the Federal and State priority areas that will be addressed under the plan in the fiscal year;

(B) describe the specific 1-year and 3-year objectives to be achieved and include a listing of the programs, activities, and resources by which the State Developmental Disabilities Council will implement its systemic change, capacity building, and advocacy activities in selected priority areas, and set forth the non-Federal share required to carry out each objective; and

(C) establish a method for the periodic evaluation of the plan's effectiveness in meeting the objectives described in subparagraph (B).

(5) **ASSURANCES.**—The plan shall contain or be supported by the assurances described in subparagraphs (A) through (N), which are satisfactory to the Secretary.

(A) **USE OF FUNDS.**—With respect to the funds paid to the State under section 125, the plan shall provide assurances that—

(i) such funds will be used to make a significant contribution toward enhancing the independence, productivity, and integration and inclusion into the community of individuals with developmental disabilities in various political subdivisions of the State;

(ii) such funds will be used to supplement and to increase the level of funds that would otherwise be made available for the purposes for which Federal funds are provided and not to supplant non-Federal funds;

(iii) such funds will be used to complement and augment rather than duplicate or replace services for individuals with developmental disabilities and their families who are eligible for Federal assistance under other State programs;

(iv) part of such funds will be made available by the State to public or private entities;

(v) not more than 25 percent of such funds will be allocated to the agency designated under section 124(d) for service demonstration by such agency and that such funds and demonstration services have been explicitly authorized by the State Developmental Disabilities Council;

(vi) not less than 65 percent of the amount available to the State under section 125 shall be expended for activities in the Federal priority area of employment activities, and, at the discretion of the State, activities in any or all of the three other Federal priority areas and an optional State priority area; and

(vii) the remainder of the amount available to the State from allotments under section 125 (after making expenditures required by clause (vi)) shall be used for the planning, coordination, administration, and implementation of priority area activities, and other activities relating to systemic change, capacity building, and advocacy to implement the responsibilities of the State Developmental Disabilities Council pursuant to section 124(c).

(B) STATE FINANCIAL PARTICIPATION.—The plan shall provide assurances that there will be reasonable State financial participation in the cost of carrying out the State plan.

(C) CONFLICT OF INTEREST.—The plan shall provide assurances that the State Developmental Disabilities Council has approved conflict of interest policies as of October 1, 1994, to ensure that no member of such Council shall cast a vote on any matter that would provide direct financial benefit to the member or otherwise give the appearance of a conflict of interest.

(D) URBAN AND RURAL POVERTY AREAS.—The plan shall provide assurances that special financial and technical assistance shall be given to organizations that provide services, supports, and other assistance to individuals with developmental disabilities who live in areas designated as urban or rural poverty areas.

(E) PROGRAM STANDARDS.—The plan shall provide assurances that programs, projects, and activities assisted under the plan, and the buildings in which such programs, projects, and activities are operated, will meet standards prescribed by the Secretary in regulation and all applicable Federal and State accessibility standards.

(F) INDIVIDUALIZED SERVICES.—The plan shall provide assurances that any direct services provided to individuals with developmental disabilities and funded under this plan will be provided in an individualized manner, consistent with unique strengths, resources, priorities, concerns, abilities, and capabilities of an individual.

(G) HUMAN RIGHTS.—The plan shall provide assurances that the human rights of all individuals with developmental disabilities (especially those individuals without familial protection) who are receiving services under pro-

grams assisted under this part will be protected consistent with section 110 (relating to rights of individuals with developmental disabilities).

(H) MINORITY PARTICIPATION.—The plan shall provide assurances that the State has taken affirmative steps to assure that participation in programs under this part is geographically representative of the State, and reflects the diversity of the State with respect to race and ethnicity.

(I) INTERMEDIATE CARE FACILITY FOR THE MENTALLY RETARDED SURVEY REPORTS.—The plan shall provide assurances that the State will provide the State Developmental Disabilities Council with a copy of each annual survey report and plan of corrections for cited deficiencies prepared pursuant to section 1902(a)(31) of the Social Security Act with respect to any intermediate care facility for the mentally retarded in such State not less than 30 days after the completion of each such report or plan.

(J) VOLUNTEERS.—The plan shall provide assurances that the maximum utilization of all available community resources including volunteers serving under the Domestic Volunteer Service Act of 1973 and other appropriate voluntary organizations will be provided for, except that such volunteer services shall supplement, and shall not be in lieu of, services of paid employees.

(K) EMPLOYEE PROTECTIONS.—The plan shall provide assurances that fair and equitable arrangements (as determined by the Secretary after consultation with the Secretary of Labor) will be provided to protect the interests of employees affected by actions under the plan to provide community living activities, including arrangements designed to preserve employee rights and benefits and to provide training and retraining of such employees where necessary and arrangements under which maximum efforts will be made to guarantee the employment of such employees.

(L) STAFF ASSIGNMENTS.—The plan shall provide assurances that the staff and other personnel of the State Developmental Disabilities Council, while working for the Council, are responsible solely for assisting the Council in carrying out its duties under this part and are not assigned duties by the designated State agency or any other agency or office of the State.

(M) NONINTERFERENCE.—The plan shall provide assurances that the designated State agency or other office of the State will not interfere with systemic change, capacity building, and advocacy activities, budget, personnel, State plan development, or plan implementation of the State Developmental Disabilities Council, except that the designated State agency shall have the authority necessary to carry out the responsibilities described in section 124(d)(3).

(N) OTHER ASSURANCES.—The plan shall contain such additional information and assurances as the Secretary may find necessary to carry out the provisions and purposes of this part.

(d) PUBLIC REVIEW, SUBMISSION, AND APPROVAL.—

(1) PUBLIC REVIEW.—The plan shall be made available for public review and comment with appropriate and sufficient notice in accessible formats and take into account and respond to significant suggestions, as prescribed by the Secretary in regulation.

(2) CONSULTATION WITH THE DESIGNATED STATE AGENCY.—Before the plan is submitted to the Secretary, the State Developmental Disabilities Council shall consult with the designated State agency to ensure that the State plan is consistent with State law and to obtain appropriate State plan assurances.

(3) PLAN APPROVAL.—The Secretary shall approve any State plan and annual updates of such plan that comply with the provisions of subsections (a), (b), and (c). The Secretary may not finally disapprove a State plan except after providing reasonable notice and an opportunity for a hearing to the State.

SEC. 124.¹ [6024] STATE DEVELOPMENTAL DISABILITIES COUNCILS AND DESIGNATED STATE AGENCIES.

(a) IN GENERAL.—Each State that receives assistance under this part shall establish and maintain a State Developmental Disabilities Council (hereafter in this section referred to as the “Council”) to promote, through systemic change, capacity building, and advocacy activities (consistent with section 101(c)(2)), the development of a consumer and family-centered comprehensive system and a coordinated array of culturally competent services, supports and other assistance designed to achieve independence, productivity, and integration and inclusion into the community for individuals with developmental disabilities. The Council shall have the authority to fulfill its responsibilities described in subsection (c).

(b) COUNCIL MEMBERSHIP.—

(1) COUNCIL APPOINTMENTS.—The members of the Council of a State shall be appointed by the Governor of the State from among the residents of that State. The Governor shall select members of the Council, at his or her discretion, after soliciting recommendations from organizations representing a broad range of individuals with developmental disabilities and individuals interested in individuals with developmental disabilities, including the non-State agency members of the Council. The Council may, at the request of the Governor, coordinate Council and public input to the Governor regarding all recommendations. To the extent feasible, the membership of the Council shall be geographically representative of the State and reflect the diversity of the State with respect to race and ethnicity.

(2) MEMBERSHIP ROTATION.—The Governor shall make appropriate provisions to rotate the membership of the Council. Such provisions shall allow members to continue to serve on the Council until such members’ successors are appointed. The Council shall notify the Governor regarding membership requirements, when vacancies remain unfilled for a significant period of time.

¹Section 123 was repealed by section 204 of Public Law 103-230 (108 Stat. 302).

(3) REPRESENTATION OF AGENCIES AND ORGANIZATIONS.—Each Council shall at all times include representatives of the principal State agencies (including the State agencies that administer funds provided under the Rehabilitation Act of 1973, the Individuals with Disabilities Education Act, the Older Americans Act, and title XIX of the Social Security Act), institutions of higher education, each university affiliated program in the State established under part D, the State protection and advocacy system established under part C, and local agencies, nongovernmental agencies, and private nonprofit groups concerned with services for individuals with developmental disabilities in the State in which such agencies and groups are located. Such representatives shall—

(A) have sufficient authority to engage in policy planning and implementation on behalf of the department, agency, or program such representatives represent; and

(B) recuse themselves from any discussion of grants or contracts for which such representatives' departments, agencies, or programs are grantees or applicants and comply with the conflict of interest policies required under section 122(c)(5)(C).

(4) REPRESENTATION OF INDIVIDUALS WITH DEVELOPMENTAL DISABILITIES.—Not less than 50 percent of the membership of each Council shall consist of individuals who are—

(A)(i) individuals with developmental disabilities;

(ii) parents or guardians of children with developmental disabilities; or

(iii) immediate relatives or guardians of adults with mentally impairing developmental disabilities who cannot advocate for themselves; and

(B) not employees of a State agency that receives funds or provides services under this part, and who are not managing employees (as defined in section 1126(b) of the Social Security Act) of any other entity that receives funds or provides services under this part.

(5) COMPOSITION OF MEMBERSHIP WITH DEVELOPMENTAL DISABILITIES.—Of the members of the Council described in paragraph (4)—

(A) one-third shall be individuals with developmental disabilities as described in paragraph (4)(A)(i);

(B) one-third shall be parents of children with developmental disabilities as described in paragraph (4)(A)(ii), and immediate relatives or guardians of adults with mentally impairing developmental disabilities as described in paragraph (4)(A)(iii); and

(C) one-third shall be a combination of individuals described in paragraph (4)(A).

(6) INSTITUTIONALIZED INDIVIDUALS.—Of the members of the Council described in paragraph (5), at least one shall be an immediate relative or guardian of an institutionalized or previously institutionalized individual with a developmental disability or an individual with a developmental disability who resides or previously resided in an institution. This paragraph

shall not apply with respect to a State if such an individual does not reside in that State.

(c) **COUNCIL RESPONSIBILITIES.**—A Council, through Council members, staff, consultants, contractors, or subgrantees, shall have the responsibilities described in paragraphs (1) through (11).

(1) **SYSTEMIC CHANGE, CAPACITY BUILDING, AND ADVOCACY ACTIVITIES.**—The Council shall serve as an advocate for individuals with developmental disabilities and conduct programs, projects, and activities that carry out the purpose under section 121.

(2) **EXAMINATION OF PRIORITY AREAS.**—Not less than once every 3 years, the Council shall examine the provision of and need for the four Federal priority areas and an optional State priority area to address, on a statewide and comprehensive basis, urgent needs for services, supports, and other assistance for individuals with developmental disabilities and their families, pursuant to section 122.

(3) **STATE PLAN DEVELOPMENT.**—The Council shall develop and submit to the Secretary the State plan required under section 122 after consultation with the designated State agency under the State plan. Such consultation shall be solely for the purposes of obtaining State assurances and ensuring consistency of the plan with State law.

(4) **STATE PLAN IMPLEMENTATION.**—The Council shall implement the State plan by conducting and supporting the Federal priority area of employment, not less than one of the remaining three Federal priority areas, and an optional State priority area as defined in section 102, through systemic change, capacity building, and advocacy activities such as those described in subparagraphs (A) through (K).

(A) **DEMONSTRATION OF NEW APPROACHES.**—The Council may conduct, on a time-limited basis, the demonstration of new approaches to enhance the independence, productivity, and integration and inclusion into the community of individuals with developmental disabilities. This may include making successful demonstrations generally available through sources of funding other than funding under this part, and may also include assisting those conducting such successful demonstration activities to develop strategies for securing funding from other sources.

(B) **OUTREACH.**—The Council may conduct activities to reach out to assist and enable individuals with developmental disabilities and their families who otherwise might not come to the attention of the Council to obtain services, supports, and other assistance, including access to special adaptation of generic services or specialized services.

(C) **TRAINING.**—The Council may conduct training for individuals with developmental disabilities, their families, and personnel (including professionals, paraprofessionals, students, volunteers, and other community members) to enable such individuals to obtain access to, or to provide, services, supports and other assistance, including special adaptation of generic services or specialized services for in-

dividuals with developmental disabilities and their families. To the extent that training activities are provided, such activities shall be designed to promote the empowerment of individuals with developmental disabilities and their families.

(D) SUPPORTING COMMUNITIES.—The Council may assist neighborhoods and communities to respond positively to individuals with developmental disabilities and their families by encouraging local networks to provide informal and formal supports and enabling communities to offer such individuals and their families access, resources, and opportunities.

(E) INTERAGENCY COLLABORATION AND COORDINATION.—The Council may promote interagency collaboration and coordination to better serve, support, assist, or advocate for individuals with developmental disabilities and their families.

(F) COORDINATION WITH RELATED COUNCILS, COMMITTEES, AND PROGRAMS.—The Council may conduct activities to enhance coordination with—

(i) other councils or committees, authorized by Federal or State law, concerning individuals with disabilities (such as the State Interagency Coordinating Council under part H of the Individuals with Disabilities Education Act, the State Rehabilitation Advisory Council and the Statewide Independent Living Council under the Rehabilitation Act of 1973, the State Mental Health Planning Council under part B of title XIX of the Public Health Service Act and other similar councils or committees);

(ii) parent training and information centers under part D of the Individuals with Disabilities Education Act and other federally funded projects that assist parents of children with disabilities; and

(iii) other groups interested in systemic change, capacity building, and advocacy for individuals with disabilities.

(G) BARRIER ELIMINATION, SYSTEMS DESIGN, AND CITIZEN PARTICIPATION.—The Council may conduct activities to eliminate barriers, enhance systems design and redesign, and enhance citizen participation to address issues identified in the State plan.

(H) PUBLIC EDUCATION AND COALITION DEVELOPMENT.—The Council may conduct activities to educate the public about the capabilities, preferences, and needs of individuals with developmental disabilities and their families and to develop and support coalitions that support the policy agenda of the Council, including training in self-advocacy, educating policymakers, and citizen leadership skills.

(I) INFORMING POLICYMAKERS.—The Council may provide information to Federal, State, and local policymakers, including the Congress, the Federal executive branch, the Governor, State legislature, and State agencies, in order to

increase the ability of such policymakers to offer opportunities and to enhance or adapt generic services or provide specialized services to individuals with developmental disabilities and their families by conducting studies and analyses, gathering information, and developing and disseminating model policies and procedures, information, approaches, strategies, findings, conclusions, and recommendations.

(J) PREVENTION.—The Council may conduct prevention activities as defined in section 102.

(K) OTHER ACTIVITIES.—The Council may conduct other systemic change, capacity building, and advocacy activities to promote the development of a consumer and family-centered comprehensive system and a coordinated array of culturally competent services, supports and other assistance designed to achieve independence, productivity, and integration and inclusion into the community of individuals with developmental disabilities throughout the State on a comprehensive basis.

(5) STATE PLAN MONITORING.—Not less than once each year, the Council shall monitor, review, and evaluate the implementation and effectiveness of the State plan in meeting such plan's objectives.

(6) REVIEW OF DESIGNATED STATE AGENCY.—The Council shall periodically review the designated State agency with respect to the activities carried out under this Act and make any recommendations for change to the Governor.

(7) REPORTS.—The Council shall submit to the Secretary, through the Governor, periodic reports on its activities as the Secretary may reasonably request, and keep such records and afford such access thereto as the Secretary finds necessary to verify such reports.

(8) BUDGET.—Each Council shall prepare, approve, and implement a budget using amounts paid to the State under this part to fund and implement all programs, projects, and activities under this part including—

(A) conducting such hearings and forums as the Council may determine to be necessary to carry out the duties of the Council, reimbursing Council members of the Council for reasonable and necessary expenses for attending Council meetings and performing Council duties (including child care and personal assistance services), paying compensation to a member of the Council, if such member is not employed or must forfeit wages from other employment, for each day such member is engaged in performing the duties of the Council, supporting Council member and staff travel to authorized training and technical assistance activities including inservice training and leadership development, and appropriate subcontracting activities;

(B) hiring and maintaining sufficient numbers and types of staff (qualified by training and experience) and obtaining the services of such professional, consulting, technical, and clerical personnel (qualified by training and experience), consistent with State law, as the Council deter-

mines to be necessary to carry out its functions under this part, except that such State shall not apply hiring freezes, reductions in force, prohibitions on staff travel, or other policies, to the extent that such policies would impact staff or functions funded with Federal funds and would prevent the Council from carrying out its functions under this Act; and

(C) directing the expenditure of funds for grants, contracts, interagency agreements that are binding contracts, and other activities authorized by the approved State plan.

(9) STAFF HIRING AND SUPERVISION.—A Council shall, consistent with State law, recruit and hire a Director of the Council, should the position of Director become vacant, and supervise and annually evaluate the Director. The Director shall hire, supervise, and annually evaluate the staff of the Council. Council recruitment and hiring of staff shall be consistent with Federal and State nondiscrimination laws. Dismissal of personnel shall be consistent with State law and personnel policies.

(10) STAFF ASSIGNMENTS.—The staff and other personnel, while working for the Council, shall be responsible solely for assisting the Council in carrying out its duties under this part and shall not be assigned duties by the designated State agency or any other agency or office of the State.

(11) CONSTRUCTION.—

(A) ACTIVITIES OF THE COUNCIL.—Nothing in this part shall be construed to preclude a Council from engaging in systemic change, capacity building, and advocacy activities for individuals with disabilities other than developmental disabilities, where appropriate.

(B) AUTHORITY OF THE COUNCIL.—Nothing in this Act shall be construed to authorize a Council to direct, control, or exercise any policymaking authority or administrative authority over any program assisted under the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.) and the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

(d) DESIGNATED STATE AGENCY.—

(1) IN GENERAL.—Each State that receives assistance under this part shall designate the State agency that shall, on behalf of the State, provide support to the Council. After the date of enactment of the Developmental Disabilities Assistance and Bill of Rights Act Amendments of 1994, any designation of a State agency shall be made in accordance with the requirements of this subsection.

(2) DESIGNATION.—

(A) TYPE OF AGENCY.—Except as provided in this subsection, the designated State agency shall be—

(i) the Council if such Council may be the designated State agency under the laws of the State;

(ii) a State agency that does not provide or pay for services made available to individuals with developmental disabilities; or

(iii) a State office, including the immediate office of the Governor of the State or a State planning office.

(B) CONDITIONS FOR CONTINUATION OF STATE SERVICE AGENCY DESIGNATION.—

(i) DESIGNATION BEFORE ENACTMENT.—If a State agency that provides or pays for services for individuals with developmental disabilities was a designated State agency for purposes of this part on the date of enactment of the Developmental Disabilities Assistance and Bill of Rights Act Amendments of 1994, and the Governor of the State (or legislature, where appropriate and in accordance with State law) determines prior to June 30, 1994, not to change the designation of such agency, such agency may continue to be a designated State agency for purposes of this part.

(ii) CRITERIA FOR CONTINUED DESIGNATION.—The determination at the discretion of the Governor (or legislature as the case may be) shall be made after the Governor has considered the comments and recommendations of the general public and a majority of the non-State agency members of the Council with respect to the designation of such State agency, and after the Governor (or legislature as the case may be) has made an independent assessment that the designation of such agency shall not interfere with the budget, personnel, priorities, or other action of the Council, and the ability of the Council to serve as an advocate for individuals with developmental disabilities.

(C) REVIEW OF DESIGNATION.—After April 1, 1994, the Council may request a review of the designation of the designated State agency by the Governor (or legislature as the case may be). The Council shall provide documentation concerning the reason the Council desires a change to be made and make a recommendation to the Governor (or legislature as the case may be) regarding a preferred designated State agency.

(D) APPEAL OF DESIGNATION.—After the review is completed under subparagraph (C), a majority of the non-State agency members of the Council may appeal to the Secretary for a review of the designation of the designated State agency if Council independence as an advocate is not assured because of the actions or inactions of the designated State agency.

(3) RESPONSIBILITIES.—The designated State agency shall, on behalf of the State, have the responsibilities described in subparagraphs (A) through (F).

(A) SUPPORT SERVICES.—The designated State agency shall provide required assurances and support services as requested by and negotiated with the Council.

(B) FISCAL RESPONSIBILITIES.—The designated State agency shall—

(i) receive, account for, and disperse funds under this part based on the State plan required in section 122; and

(ii) provide for such fiscal control and fund accounting procedures as may be necessary to assure the proper disbursement of, and accounting for, funds paid to the State under this part.

(C) RECORDS, ACCESS, AND FINANCIAL REPORTS.—The designated State agency shall keep such records and afford access thereto as the Secretary and the Council determine necessary. The designated State agency, if other than the Council, shall provide timely financial reports at the request of the Council regarding the status of expenditures, obligations, liquidation, and the Federal and non-Federal share.

(D) NON-FEDERAL SHARE.—The designated State agency, if other than the Council, shall provide the required non-Federal share defined in section 125A(c).

(E) ASSURANCES.—The designated State agency shall assist the Council in obtaining the appropriate State plan assurances and in ensuring that the plan is consistent with State law.

(F) MEMORANDUM OF UNDERSTANDING.—On the request of the Council, the designated State agency shall enter into a memorandum of understanding with the Council delineating the roles and responsibilities of the designated State agency.

(4) USE OF FUNDS FOR DESIGNATED STATE AGENCY RESPONSIBILITIES.—

(A) NECESSARY EXPENDITURES OF STATE DESIGNATED AGENCY.—At the request of any State, a portion of any allotment or allotments of such State under this part for any fiscal year shall be available to pay up to one-half (or the entire amount if the Council is the designated State agency) of the expenditures found necessary by the Secretary for the proper and efficient exercise of the functions of the State designated agency, except that not more than 5 percent of the total of the allotments of such State for any fiscal year, or \$50,000, whichever is less, shall be made available for the total expenditure for such purpose by the State agency designated under this subsection.

(B) CONDITION FOR FEDERAL FUNDING.—Amounts shall be provided under subparagraph (A) to a State for a fiscal year only on condition that there shall be expended from State sources for carrying out the responsibilities of the designated State agency under paragraph (3) not less than the total amount expended for carrying out such responsibilities from such sources during the previous fiscal year, except in such year as the Council may become the designated State agency.

(C) SUPPORT SERVICES PROVIDED BY OTHER AGENCIES.—With the agreement of the designated State agency, the Council may use or contract with agencies other than the designated State agency to perform the functions of the designated State agency.

(e) 1990 REPORT.—Not later than January 1, 1990, each Council shall complete the reviews, analyses, and final report described in this section.

(1) COMPREHENSIVE REVIEW AND ANALYSIS.—Each Council shall conduct a comprehensive review and analysis of the eligibility for services provided, and the extent, scope, and effectiveness of, services provided and functions performed by, all State agencies (including agencies that provide public assistance) that affect or that potentially affect the ability of individuals with developmental disabilities to achieve the goals of independence, productivity, and integration and inclusion into the community, including individuals with developmental disabilities attributable to physical impairment, mental impairment, or a combination of physical and mental impairments.

(2) CONSUMER SATISFACTION.—Each Council shall conduct a review and analysis of the effectiveness of, and consumer satisfaction with, the functions performed by, and services provided or paid for from Federal and State funds by, each of the State agencies (including agencies that provide public assistance) responsible for performing functions for, and providing services to, all individuals with developmental disabilities in the State. Such review and analysis shall be based upon a survey of a representative sample of individuals with developmental disabilities receiving services from each such agency, and if appropriate, shall include such individuals' families.

(3) PUBLIC REVIEW AND COMMENT.—Each Council shall convene public forums, after the provision of notice within the State, in order to—

(A) present the findings of the reviews and analyses prepared under paragraphs (1) and (2);

(B) obtain comments from all interested individuals in the State regarding the unserved and underserved populations of individuals with developmental disabilities that result from physical impairment, mental impairment, or a combination of physical and mental impairments; and

(C) obtain comments on any proposed recommendations concerning the removal of barriers to services for individuals with developmental disabilities and to connect such services to existing State agencies by recommending the designation of one or more State agencies, as appropriate, to be responsible for the provision and coordination of such services.

(4) BASIS FOR STATE PLAN.—Each Council shall utilize the information developed pursuant to paragraphs (1), (2), and (3) in developing the State plan.

SEC. 125. [6025] STATE ALLOTMENTS.

(a) ALLOTMENTS.—

(1) IN GENERAL.—For each fiscal year, the Secretary shall, in accordance with regulations and this paragraph, allot the sums appropriated for such year under section 130 among the States on the basis of—

(A) the population,

(B) the extent of need for services for persons with developmental disabilities, and

(C) the financial need,

of the respective States. Sums allotted to the States under this section shall be used in accordance with approved State plans under section 122 for the provision under such plans of services for persons with developmental disabilities.

(2) ADJUSTMENTS.—Adjustments in the amounts of State allotments based on subparagraphs (A), (B), and (C) of paragraph (1) shall be made not more often than annually. The Secretary shall notify States of any adjustment made and the percentage of the total appropriation for each State not less than six months before the beginning of the fiscal year in which such adjustment is to take effect.

(3) MINIMUM ALLOTMENT FOR APPROPRIATIONS LESS THAN OR EQUAL TO \$75,000,000.—

(A) IN GENERAL.—Except as provided in paragraph (4), for any fiscal year the allotment under this section—

(i) to each of American Samoa, Guam, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, or the Republic of Palau (until the Compact of Free Association with Palau takes effect) may not be less than the greater of—

(I) \$210,000; or

(II) the greater of the allotment received by such State for fiscal year 1992, or the allotment received by such State for fiscal year 1993, under this section (determined without regard to subsection (d)); and

(ii) to any State not described in clause (i), may not be less than the greater of—

(I) \$400,000; or

(II) the greater of the allotment received by such State for fiscal year 1992, or the allotment received by such State for fiscal year 1993, under this section (determined without regard to subsection (d)).

(B) REDUCTION OF ALLOTMENT.—Notwithstanding subparagraph (A), if the aggregate of the amounts to be allotted to each State pursuant to subparagraph (A) in any fiscal year exceeds the total amount appropriated under section 130 for such fiscal year, the amount to be allotted to a State for such fiscal year shall be an amount which bears the same ratio to the amount which is to be allotted to the State pursuant to such subparagraph as the total amount appropriated under section 130 for such fiscal years bears to the total of the amount required to be appropriated under such section for allotments to provide each State with the allotment required by such subparagraph.

(4) MINIMUM ALLOTMENT FOR APPROPRIATIONS IN EXCESS OF \$75,000,000.—

(A) IN GENERAL.—In any case in which amounts appropriated under section 130 for a fiscal year exceeds

\$75,000,000, the allotment under this section for such fiscal year—

(i) to each of American Samoa, Guam, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands or the Republic of Palau (until the Compact of Free Association with Palau takes effect) may not be less than the greater of—

(I) \$220,000; or

(II) the greater of the allotment received by such State for fiscal year 1992, or the allotment received by such State for fiscal year 1993, under this section (determined without regard to subsection (d)); and

(ii) to any State not described in clause (i) may not be less than the greater of—

(I) \$450,000; or

(II) the greater of the allotment received by such State for fiscal year 1992, or the allotment received by such State for fiscal year 1993, under this section (determined without regard to subsection (d)).

(B) REDUCTION OF ALLOTMENT.—The requirements of paragraph (3)(B) shall apply with respect to amounts to be allotted to States under subparagraph (A), in the same manner and to the same extent as such requirements apply with respect to amounts to be allotted to States under paragraph (3)(A).

(5) STATE SUPPORTS, SERVICES, AND OTHER ACTIVITIES.—In determining, for purposes of paragraph (1)(B), the extent of need in any State for services for persons with developmental disabilities, the Secretary shall take into account the scope and extent of the services described, pursuant to section 122(c)(3)(A), in the State plan of the State.

(6) INCREASE IN ALLOTMENTS.—In any case in which the total amount appropriated under section 130 for a fiscal year exceeds the total amount appropriated under such section for the preceding fiscal year by a percentage greater than the most recent percentage change in the Consumer Price Index published by the Secretary of Labor under section 100(c)(1) of the Rehabilitation Act of 1973, the Secretary shall increase each of the minimum allotments under paragraphs (3) and (4) by an amount which bears the same ratio to the amount of such minimum allotment (including any increases in such minimum allotment under this paragraph for prior fiscal years) as the amount which is equal to the difference between—

(A) the total amount appropriated under section 130 for the fiscal year for which the increase in minimum allotment is being made, minus

(B) the total amount appropriated under section 130 for the immediately preceding fiscal year, bears to the total amount appropriated under section 130 for such preceding fiscal year.

(b) UNOBLIGATED FUNDS.—Any amount paid to a State for a fiscal year and remaining unobligated at the end of such year shall

remain available to such State for the next fiscal year for the purposes for which such amount was paid.

(c) **OBLIGATION OF FUNDS.**—For the purposes of this part, State Interagency Agreements are considered valid obligations for the purpose of obligating Federal funds allotted to the State under this part.

(d) **COOPERATIVE EFFORTS BETWEEN STATES.**—Whenever the State plan approved in accordance with section 122 provides for cooperative or joint effort between States or between or among agencies, public or private, in more than one State, portions of funds allotted to one or more such cooperating States may be combined in accordance with the agreements between the agencies involved.

(e) **REALLOTMENTS.**—The amount of an allotment to a State for a fiscal year which the Secretary determines will not be required by the State during the period for which it is available for the purpose for which allotted shall be available for reallocation by the Secretary from time to time, on such date or dates as the Secretary may fix (but not earlier than thirty days after the Secretary has published notice of the intention of the Secretary to make such reallocation in the Federal Register), to other States with respect to which such a determination has not been made, in proportion to the original allotments of such States for such fiscal year, but with such proportionate amount for any of such other States being reduced to the extent it exceeds the sum the Secretary estimates such State needs and will be able to use during such period; and the total of such reductions shall be similarly reallocated among the States whose proportionate amounts were not so reduced. Any amount so reallocated to a State for a fiscal year shall be deemed to be a part of its allotment under subsection (a) for such fiscal year.

SEC. 125A. [6025a] FEDERAL AND NON-FEDERAL SHARE.

(a) **AGGREGATE COSTS.**—The Federal share of all projects in a State supported by an allotment to the State under this part may not exceed 75 percent of the aggregate necessary costs of all such projects as determined by the Secretary, except that—

(1) in the case of projects whose activities or products target individuals with developmental disabilities who live in urban or rural poverty areas, the Federal share of all such projects may not exceed 90 percent of the aggregate necessary costs of such projects or activities, as determined by the Secretary; and

(2) in the case of projects or activities undertaken by the Council or Council staff to implement State plan priority activities, the Federal share of all such activities may be up to 100 percent of the aggregate necessary costs of such activities.

(b) **NONDUPLICATION.**—In determining the amount of any State's Federal share of the expenditures incurred by such State under a State plan approved under section 122, the Secretary shall not consider—

(1) any portion of such expenditures that are financed by Federal funds provided under any provision of law other than section 125; and

(2) the amount of any non-Federal funds required to be expended as a condition of receipt of such Federal funds.

(c) NON-FEDERAL SHARE.—

(1) **IN KIND CONTRIBUTIONS.**—The non-Federal share of the cost of any project assisted by a grant or an allotment under this part may be provided in kind.

(2) **CONTRIBUTIONS OF POLITICAL SUBDIVISIONS, PUBLIC, OR PRIVATE ENTITIES.—**

(A) **IN GENERAL.**—Expenditures on projects or activities by a political subdivision of a State or by a public or private entity shall, subject to such limitations and conditions as the Secretary may by regulation prescribe, be considered to be expenditures by such State in the case of a project under this part.

(B) **STATE CONTRIBUTIONS.**—State contributions, including contributions by the designated State agency to provide support services to the Council pursuant to section 124(d)(4), may be counted as part of such State's non-Federal share of allotments under this part.

(3) **VARIATIONS OF THE NON-FEDERAL SHARE.**—The non-Federal share required on a grant-by-grant basis may vary.

SEC. 126. [6026] PAYMENTS TO THE STATES FOR PLANNING, ADMINISTRATION, AND SERVICES.

(a) **STATE PLAN EXPENDITURES.**—From each State's allotments for a fiscal year under section 125, the State shall be paid the Federal share of the expenditures, other than expenditures for construction, incurred during such year under its State plan approved under this part. Such payments shall be made from time to time in advance on the basis of estimates by the Secretary of the sums the State will expend under the State plan, except that such adjustments as may be necessary shall be made on account of previously made underpayments or overpayments under this section.

(b) **SUPPORT SERVICES.**—Payments to States for support services provided by the designated State agency pursuant to section 124(d)(4) may be made in advance or by way of reimbursement, and in such installments as the Secretary may determine.

SEC. 127. [6027] WITHHOLDING OF PAYMENTS FOR PLANNING, ADMINISTRATION, AND SERVICES.

Whenever the Secretary, after reasonable notice and opportunity for hearing to the State Planning Council and the appropriate State agency designated pursuant to section 122(b)(1) finds that—

(1) there is a failure to comply substantially with any of the provisions required by section 122 to be included in the State plan, particularly section 122(b)(3) or 122(f); or

(2) there is a failure to comply substantially with any regulations of the Secretary which are applicable to this part, the Secretary shall notify such State Council and agency or agencies that further payments will not be made to the State under section 125 (or, in the discretion of the Secretary, that further payments will not be made to the State under section 125 for activities in which there is such failure), until the Secretary is satisfied that there will no longer be such failure. Until the Secretary is so satis-

fied, the Secretary shall make no further payment to the State under section 125, or shall limit further payment under section 125 to such State to activities in which there is no such failure.

SEC. 129.¹ [6029] APPEALS BY STATES.

If any State is dissatisfied with the Secretary's action under section 122(c) or section 127, such State may appeal to the United States court of appeals for the circuit in which such State is located, by filing a petition with such court within sixty days after such action. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by the Secretary for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based the action, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have jurisdiction to affirm the action of the Secretary or to set it aside, in whole or in part, temporarily or permanently, but until the filing of the record, the Secretary may modify or set aside the order of the Secretary. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive, but the court, for good cause shown, may remand the case to the Secretary to take further evidence, and the Secretary may thereupon make new or modified findings of the fact and may modify the previous action of the Secretary, and shall file in the court the record of the further proceedings. Such new or modified findings of fact shall likewise be conclusive if supported by substantial evidence. The judgment of the court affirming or setting aside, in whole or in part, any action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28, United States Code. The commencement of proceedings under this section shall not, unless so specifically ordered by the court, operate as a stay of the Secretary's action.

AUTHORIZATION OF APPROPRIATIONS

SEC. 130. [6030] For allotments under section 125, there are authorized to be appropriated \$70,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

PART C—PROTECTION AND ADVOCACY OF INDIVIDUAL RIGHTS

SEC. 141. [6041] PURPOSE.

It is the purpose of this part to provide for allotments to support a Protection and Advocacy system (hereafter referred to in this part as the "system") in each State to protect the legal and human rights of individuals with developmental disabilities in accordance with section 142.

¹ Section 128 was repealed by section 210 of Public Law 103-230 (108 Stat. 313).

SEC. 142. [6042] SYSTEM REQUIRED.

(a) **SYSTEM REQUIRED.**—In order for a State to receive an allotment under part B—

(1) the State must have in effect a system to protect and advocate the rights of individuals with developmental disabilities;

(2) such system must—

(A) have the authority to—

(i) pursue legal, administrative, and other appropriate remedies or approaches to ensure the protection of, and advocacy for, the rights of such individuals within the State who are or who may be eligible for treatment, services, or habilitation, or who are being considered for a change in living arrangements, with particular attention to members of ethnic and racial minority groups; and

(ii) provide information on and referral to programs and services addressing the needs of individuals with developmental disabilities;

(B) have the authority to investigate incidents of abuse and neglect of individuals with developmental disabilities if the incidents are reported to the system or if there is probable cause to believe that the incidents occurred;

(C) on an annual basis, develop a statement of objectives and priorities for the system's activities; and

(D) on an annual basis, provide to the public, including individuals with developmental disabilities attributable to either physical impairment, mental impairment, or a combination of physical or mental impairments, and their representatives, as appropriate, non-State agency representatives of the State Developmental Disabilities Council, and the university affiliated program (if applicable within a State), an opportunity to comment on—

(i) the objectives and priorities established by the system and the rationale for the establishment of such objectives; and

(ii) the activities of the system, including the coordination with the advocacy programs under the Rehabilitation Act of 1973, the Older Americans Act of 1965, and the Protection and Advocacy for Mentally Ill Individuals Act of 1986, and with other related programs, including the parent training and information centers, education ombudsman programs and assistive technology projects;

(E) establish a grievance procedure for clients or prospective clients of the system to assure that individuals with developmental disabilities have full access to services of the system;

(F) not be administered by the State Developmental Disabilities Council authorized under part B;

(G) be independent of any agency which provides treatment, services, or habilitation to individuals with developmental disabilities;

(H) have access at reasonable times and locations to any resident who is an individual with a developmental disability in a facility that is providing services, supports, and other assistance to such a resident;

(I) have access to all records of—

(i) any individual with developmental disabilities who is a client of the system if such individual, or the legal guardian, conservator, or other legal representative of such individual, has authorized the system to have such access;

(ii) any individual with developmental disabilities—

(I) who, by reason of such individual's mental or physical condition, is unable to authorize the system to have such access;

(II) who does not have a legal guardian, conservator, or other legal representative, or for whom the legal guardian is the State; and

(III) with respect to whom a complaint has been received by the system or with respect to whom as a result of monitoring or other activities there is probable cause to believe that such individual has been subject to abuse or neglect; and

(iii) any person with a developmental disability who has a legal guardian, conservator, or other legal representative with respect to whom a complaint has been received by the system or with respect to whom there is probable cause to believe the health or safety of the individual is in serious and immediate jeopardy whenever—

(I) such representatives have been contacted by such system upon receipt of the name and address of such representatives;

(II) such system has offered assistance to such representatives to resolve the situation; and

(III) such representatives have failed or refused to act on behalf of the individual;

(J) hire and maintain sufficient numbers and types of staff, qualified by training and experience, to carry out such system's function except that such State shall not apply hiring freezes, reductions in force, prohibitions on staff travel, or other policies, to the extent that such policies would impact staff or functions funded with Federal funds and would prevent the system from carrying out its functions under this Act;

(K) have the authority to educate policymakers; and

(L) provide assurances to the Secretary that funds allotted to the State under this section will be used to supplement and increase the level of funds that would otherwise be made available for the purposes for which Federal funds are provided and not to supplant such non-Federal funds;

(3) the State must provide to the system a copy of each annual survey report and plan of corrections for cited deficiencies

made pursuant to section 1902(a)(31) of the Social Security Act with respect to any intermediate care facility for the mentally retarded in the State within 30 days after the completion of each such report or plan; and

(4) the agency implementing the system will not be redesignated unless there is good cause for the redesignation and unless—

(A) notice has been given of the intention to make such redesignation to the agency that is serving as the system including the good cause for such redesignation and the agency has been given an opportunity to respond to the assertion that good cause has been shown;

(B) timely notice and opportunity for public comment in an accessible format has been given to individuals with developmental disabilities or their representatives; and

(C) the system has the opportunity to appeal to the Secretary that the redesignation was not for good cause.

(b) AMERICAN INDIAN CONSORTIUM.—Upon application to the Secretary, an American Indian consortium, as defined in section 102, established to provide protection and advocacy services under this part, shall receive funding pursuant to subsection (c)(5). Such consortium shall coordinate activities with existing systems.

(c) ALLOTMENTS.—

(1) IN GENERAL.—To assist States in meeting the requirements of subsection (a), the Secretary shall allot to the States the amounts appropriated under section 143. Allotments and reallootments of such sums shall be made on the same basis as the allotments and reallootments are made under the first sentence of subsection (a)(1) and subsection (d) of section 125, except that in any case in which—

(A) the total amount appropriated under section 143 for a fiscal year is at least \$20,000,000—

(i) the allotment of each of American Samoa, Guam, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, and the Republic of Palau (until the Compact of Free Association with Palau takes effect) for such fiscal year may not be less than the greater of—

(I) \$107,000; or

(II) the greater of the allotment received by such State for fiscal year 1992, or the allotment received by such State for fiscal year 1993, under this section (determined without regard to subsection (d)); and

(ii) the allotment of any State not described in clause (i) for such fiscal year may not be less than the greater of—

(I) \$200,000; or

(II) the greater of the allotments received by such State for fiscal year 1992, or the allotment received by such State for fiscal year 1993, under this section (determined without regard to subsection (d)).

(B) the total amount appropriated under section 143 for a fiscal year is less than \$20,000,000—

(i) the allotment of each of American Samoa, Guam, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, and the Republic of Palau (until the Compact of Free Association with Palau takes effect) for such fiscal year may not be less than the greater of—

(I) \$80,000; or

(II) the greater of the allotment received by such State for fiscal year 1992, or the allotment received by such State for fiscal year 1993, under this section (determined without regard to subsection (d)); and

(ii) the allotment of any State not described in clause (i) for such fiscal year may not be less than the greater of—

(I) \$150,000; or

(II) the greater of the allotment received by such State for fiscal year 1992, or the allotment received by such State for fiscal year 1993, under this section (determined without regard to subsection (d)).

(2) INCREASE IN ALLOTMENTS.—In any case in which the total amount appropriated under section 143 for a fiscal year exceeds the total amount appropriated under such section for the preceding fiscal year by a percentage greater than the most recent percentage change in the Consumer Price Index published by the Secretary of Labor under section 100(c)(1) of the Rehabilitation Act of 1973, the Secretary shall increase each of the minimum allotments under subparagraphs (A) and (B) of paragraph (1) by an amount which bears the same ratio to the amount of such minimum allotment (including any increases in such minimum allotment under this paragraph for prior fiscal years) as the amount which is equal to the difference between—

(A) the total amount appropriated under section 143 for the fiscal year for which the increase in minimum allotment is being made, minus

(B) the total amount appropriated under section 143 for the immediately preceding fiscal year,

bears to the total amount appropriated under section 143 for such preceding fiscal year.

(3) MONITORING THE ADMINISTRATION OF THE SYSTEM.—A State may use not more than 5 percent of any allotment under this subsection for the costs of monitoring the administration of the system required under subsection (a).

(4) REDUCTION OF ALLOTMENT.—Notwithstanding paragraph (1), if the aggregate of the amounts of the allotments to be made in accordance with such paragraph for any fiscal year exceeds the total of the amounts appropriated for such allotments under section 143, the amount of a State's allotment for such fiscal year shall bear the same ratio to the amount otherwise determined under such paragraph as the total of the

amounts appropriated for that year under section 143 bears to the aggregate amount required to make an allotment to each of the States in accordance with paragraph (1).

(5) TECHNICAL ASSISTANCE AND AMERICAN INDIAN CONSORTIUM.—In any case in which amounts appropriated under section 143 for a fiscal year exceeds \$24,500,000, the Secretary shall—

(A) use not more than 2 percent of the amounts appropriated to provide technical assistance (consistent with requests by such systems for such assistance in the year that appropriations reach \$24,500,000) to eligible systems with respect to activities carried out under this title; and

(B) provide grants in accordance with paragraph (1)(A)(i) to American Indian Consortiums to provide protection and advocacy services.

(d) UNOBLIGATED FUNDS.—Any amount paid to a State for a fiscal year and remaining unobligated at the end of such year shall remain available to such State for the next fiscal year for the purposes for which such amount was paid.

(e) GOVERNING BOARD.—In States in which the system is organized as a private nonprofit entity with a multimember governing board, or a public system with a multimember governing board, such governing board shall be selected according to the policies and procedures of the system, except that—

(1) the governing board shall be composed of members who broadly represent or are knowledgeable about the needs of the individuals served by the system and include individuals with developmental disabilities who are eligible for services, or have received or are receiving services, or parents, family members, guardians, advocates, or authorized representatives of such individuals;

(2) not more than $\frac{1}{3}$ of the membership of the governing board may be appointed by the chief executive officer of the State involved, in the case of any State in which such officer has the authority to appoint the membership of the board;

(3) any vacancy in the board shall be filled not later than 60 days after the date on which the vacancy occurs; and

(4) in States in which the system is organized as a public system without a multimember governing or advisory board, the system shall establish an advisory council that shall—

(A) advise the system on policies and priorities to be carried out in protecting and advocating the rights of individuals with developmental disabilities; and

(B) consist of a majority of individuals with developmental disabilities who are eligible for services, or have received or are receiving services, or parents, family members, guardians, advocates, or authorized representatives of such individuals.

(f) RECORDS.—As used in this section the term “records” includes reports prepared or received by any staff of a facility rendering care or treatment, or reports prepared by an agency or staff person charged with investigating reports of incidents of abuse or neglect, injury or death occurring at such facility that describes incidents of abuse, neglect, injury or death occurring at such facility

and the steps taken to investigate such incidents, and discharge planning records.

(g) ACCESS TO RECORDS.—If the laws of a State prohibit a system from obtaining access to records of individuals with developmental disabilities the provisions of subparagraph (A) of paragraph (2) of subsection (a) shall not apply to such system before—

(1) the date such system is no longer subject to such prohibition; or

(2) the expiration of the 1-year period beginning on the date of enactment of this Act¹, whichever occurs first.

(h) LEGAL ACTION.—

(1) IN GENERAL.—Nothing in this Act shall preclude the systems described under this section from bringing a suit on behalf of individuals with developmental disabilities against a State, or agencies or instrumentalities of a State.

(2) USE OF AMOUNTS FROM JUDGMENT.—Amounts received pursuant to paragraph (1) through court judgments and used by the system are limited to furthering the purpose of this part and shall not be used to augment payments to legal contractors or to award personal bonuses.

(i) PAYMENT TO SYSTEMS.—Notwithstanding any other provision of law, the Secretary shall pay directly to any system which complies with the provisions of this section the amount of such system's allotment under this section, unless the system delegates otherwise.

(j) DISCLOSURE OF INFORMATION.—For purposes of any periodic audit, report, or evaluation required under this Act, the Secretary shall not require a program to disclose the identity of, or any other personally identifiable information related to, any individual requesting assistance under such program.

(k) PUBLIC NOTICE OF FEDERAL ONSITE REVIEW.—The Secretary shall provide advance public notice of any Federal programmatic and administrative review and solicit public comment on the system funded under this part through such notice. The findings of the public comment solicitation notice shall be included in the onsite visit report. The results of such review shall be distributed to the Governor of the State and to other interested public and private parties.

SEC. 143. [6043] AUTHORIZATION OF APPROPRIATIONS.

For allotments under section 142, there are authorized to be appropriated \$24,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

PART D—UNIVERSITY AFFILIATED PROGRAMS

SEC. 151. [6061] PURPOSE AND SCOPE OF ACTIVITIES.

The purpose of this part is to provide for grants to university affiliated programs that are interdisciplinary programs operated by

¹So in original. Subsection (g) was added by section 15(3) of Public Law 101-496 (104 Stat. 1199), which was enacted on October 31, 1990. The term "this Act", however, is a reference to Public Law 88-164, which was enacted on October 31, 1963. Subsection (g) above is in title I of such Public Law, and that title was added by Public Law 98-527, which was enacted on October 19, 1984. (Subsection (g) formerly was subsection (f), and was redesignated as subsection (g) by section 303(b)(9) of Public Law 103-230 (108 Stat. 319).)

universities, or by public or nonprofit entities associated with a college or university, to provide a leadership role in the promotion of independence, productivity, and integration and inclusion into the community of individuals with developmental disabilities through the provision of the following activities, which are conducted in a culturally competent manner:

(1) Interdisciplinary preservice preparation of students and fellows, including the preparation of leadership personnel.

(2) Community service activities that shall include community training and technical assistance for or with individuals with developmental disabilities, family members of individuals with developmental disabilities, professionals, paraprofessionals, students, and volunteers. Such activities may include state-of-the-art direct services including family support, individual support, personal assistance services, educational, vocational, clinical, health, prevention, or other direct services.

(3) Dissemination of information and research findings, which may include the empirical validation of activities relevant to the purposes described in paragraphs (1) and (2) and contributions to the development of new knowledge in the field of developmental disabilities.

SEC. 152. [6062] GRANT AUTHORITY.

(a) ADMINISTRATION AND OPERATION.—From appropriations under section 154(a), the Secretary shall make grants to university affiliated programs to assist in the administration and operation of the activities described in section 151. Grants may be awarded for a period not to exceed 5 years.

(b) TRAINING PROJECTS.—

(1) IN GENERAL.—From amounts appropriated under section 156(a), the Secretary shall make grants to university affiliated programs receiving grants under subsection (a) to support training projects to train personnel to address the needs of individuals with developmental disabilities in areas of emerging national significance, as described in paragraph (3). Grants awarded under this subsection shall be awarded on a competitive basis and may be awarded for a period not to exceed 5 years.

(2) ELIGIBILITY LIMITATIONS.—A university affiliated program shall not be eligible to receive funds for training projects under this subsection unless—

(A) such program has operated for at least 1 year; or

(B) the Secretary determines that such program has demonstrated the capacity to develop an effective training project during the first year such program is operated.

(3) AREAS OF FOCUS.—Training projects under this subsection shall train personnel to address the needs of individuals with developmental disabilities in the areas of emerging national significance described in subparagraphs (A) through (H).

(A) EARLY INTERVENTION.—Grants under this subsection for training projects with respect to early intervention services shall be for the purpose of assisting university affiliated programs in providing training to family

members of children with developmental disabilities and personnel from all disciplines involved with interdisciplinary intervention to infants, toddlers, and preschool age children with developmental disabilities. Such training projects shall include instruction on family-centered, community-based, coordinated care for infants, toddlers, and preschool age children with developmental disabilities and their families.

(B) AGING.—Grants under this subsection for training projects with respect to aging and developmental disabilities shall be for the purpose of supporting the planning, design, and implementation of coordinated interdisciplinary training programs between existing aging or gerontological programs and university affiliated programs in order to prepare professional staff to provide services for aging individuals with developmental disabilities and their families.

(C) COMMUNITY SERVICES.—Grants under this subsection for training projects with respect to community services shall be for the purpose of providing training that enhances direct supports and services for individuals with developmental disabilities, including training to community members, families, individuals with developmental disabilities, and community-based direct service providers. The Secretary shall ensure that all grants under this subparagraph are made only to university affiliated programs that involve community-level direct support services in the preparation of the application for such grant and that assure that any training under the university affiliated program will be coordinated with local community services and support systems and with State, local, and regional governmental or private agencies responsible for the planning or delivery of services to individuals with developmental disabilities.

(D) POSITIVE BEHAVIORAL SUPPORTS.—Grants awarded under this subsection for training projects with respect to positive behavioral supports shall be for the purpose of assisting university affiliated programs in providing training to family members of individuals with developmental disabilities and personnel in methods of developing individual supports that maximize opportunities for independence, productivity, and integration and inclusion into the community for individuals with developmental disabilities and severe behavior problems. Such training projects shall provide training to—

(i) address ethical and legal principles and standards, including the role of personal and cultural values in designing assessments and interventions;

(ii) address appropriate assessment approaches that examine the range of factors that contribute to problem behavior;

(iii) address the development of a comprehensive plan that considers the needs and preferences of an individual with a developmental disability;

(iv) address the competence in the types of skills training, environmental modification, and incentive procedures that encourage alternative behaviors;

(v) familiarize training participants with crisis intervention approaches and the separate role of such approaches as short-term emergency procedures;

(vi) familiarize training participants with medical interventions and how to evaluate the effect of such interventions on behavior; and

(vii) address techniques for evaluating the outcomes of interventions.

(E) ASSISTIVE TECHNOLOGY SERVICES.—Grants under this subsection for training projects with respect to assistive technology services shall be for the purpose of assisting university affiliated programs in providing training to personnel who provide, or will provide, assistive technology services and devices to individuals with developmental disabilities and their families. Such projects may provide training and technical assistance to improve access to assistive technology services for individuals with developmental disabilities and may include stipends and tuition assistance for training project participants. Such projects shall be coordinated with State technology coordinating councils wherever such councils exist.

(F) AMERICANS WITH DISABILITIES ACT.—Grants under this subsection for training projects with respect to the provisions of the Americans with Disabilities Act of 1990 shall be for the purpose of assisting university affiliated programs in providing training to personnel who provide, or will provide, services to individuals with developmental disabilities, and to others concerned with individuals with developmental disabilities.

(G) COMMUNITY TRANSITION.—Grants under this subsection for training projects with respect to transition from school to adult life shall be for the purpose of assisting university affiliated programs in providing training to individuals with developmental disabilities and their families, generic community agencies, advocacy organizations, and others in order to stimulate the development and improvement of policies, procedures, systems, and other mechanisms that prepare youth with developmental disabilities to enter adult life. Such projects shall be coordinated with State transition projects funded under section 626(e) of the Individuals with Disabilities Education Act, where such State transition projects exist.

(H) OTHER AREAS.—Grants under this subsection for training projects with respect to programs in other areas of national significance shall be for the purpose of training personnel in an area of special concern to the university affiliated program, and shall be developed in consultation with the State Developmental Disabilities Council.

(4) COURSES, TRAINEESHIPS AND FELLOWSHIPS.—Grants under this subsection may be used by university affiliated programs to—

(A) assist in paying the costs of courses of training or study for personnel to provide services for individuals with developmental disabilities and their families; and

(B) establish fellowships or traineeships providing such stipends and allowances as may be determined by the Secretary.

(5) PROHIBITED ACTIVITIES.—Grants awarded under this subsection shall not be used for administrative expenses for the university affiliated program under subsection (a).

(6) CRITERIA.—Grants awarded under this subsection shall meet the criteria described in subparagraphs (A) and (B).

(A) APPLICATION.—An application that is submitted for a grant under this subsection shall present evidence that training projects assisted by funds awarded under this section are—

(i) competency and value based;

(ii) designed to facilitate independence, productivity, and integration and inclusion for individuals with developmental disabilities; and

(iii) evaluated utilizing state-of-the-art evaluation techniques in the programmatic areas selected.

(B) GENERAL PROJECT REQUIREMENTS.—Training projects under this subsection shall—

(i) represent state-of-the-art techniques in areas of critical shortage of personnel that are identified through consultation with the consumer advisory committee described in section 153(d) and the State Developmental Disabilities Council;

(ii) be conducted in consultation with the consumer advisory committee described in section 153(d) and the State Developmental Disabilities Council;

(iii) be integrated into the appropriate university affiliated program and university curriculum;

(iv) be integrated with relevant State agencies in order to achieve an impact on statewide personnel and service needs;

(v) to the extent practical, be conducted in environments where services are actually delivered;

(vi) to the extent possible, be interdisciplinary in nature;

(vii) utilize strategies to recruit and train members from racial and ethnic minority backgrounds and individuals with disabilities; and

(viii) address the issue of cultural competence in the training provided.

(c) SUPPLEMENTAL AWARDS.—From amounts appropriated under section 156(a), the Secretary may make grants to university affiliated programs receiving grants under subsection (a) to support one or more of the following activities:

(1) The provision of interdisciplinary training, community training and technical assistance, community services, or dissemination of information to individuals with developmental disabilities, family members of such individuals, professionals,

volunteers, or other personnel to enable such individuals, family members, professionals, volunteers, or personnel to provide services to increase or maintain the independence, productivity, and integration and inclusion into the community of individuals with developmental disabilities and not otherwise specified in subsection (b).

(2) The conduct of an applied research program designed to produce more efficient and effective methods for the delivery of services to individuals with developmental disabilities, and the training of professionals, paraprofessionals, and family members who provide such services.

(d) **FEASIBILITY STUDIES.**—From amounts appropriated under section 156(a), the Secretary may make a grant to a university or a public or nonprofit entity which is associated with, or is an integral part of, a college or university, to study the feasibility of establishing a university affiliated program. Such study shall include an assessment of the needs of the area in which the university is located for such a program or center. The amount of a grant under this subsection may not exceed \$35,000 for any fiscal year. A grant under this subsection may only be made in a State in which there is no university affiliated program.

SEC. 153. [6063] APPLICATIONS.

(a) **IN GENERAL.**—No grants may be made under section 152(a) unless an application therefor is submitted to, and approved by, the Secretary. Such an application shall be submitted in such form and manner, and contain such information, as the Secretary may require.

(b) **STANDARDS.**—Not later than 12 months after the date of the enactment of the Developmental Disabilities Assistance and Bill of Rights Act Amendments of 1994,¹ the Secretary shall establish by regulation standards for university affiliated programs. Such standards shall reflect the special needs of all individuals with developmental disabilities who are of various ages, and shall include performance standards relating to each of the activities described in section 151.

(c)² No grants may be made under section 152(a) unless an application therefor is submitted to, and approved by, the Secretary. Such an application shall be submitted in such form and manner, and contain such information, as the Secretary may require. Such an application shall be approved by the Secretary only if the application contains or is supported by reasonable assurances that—

(1) the making of the grant will—

(A) not result in any decrease in the use of State, local, and other non-Federal funds for services for individuals with developmental disabilities and for training of in-

¹ Enacted April 6, 1994.

² Section 404(b)(2)(A) of Public Law 103-230 (108 Stat. 324) provides that the subsection is amended in the matter preceding paragraph (1) by striking "No grants" and all that follows through "Such an application" and inserting certain language. The amendment cannot be executed because the amendatory instructions do not specify to which instance of the term "Such an application" the amendment applies.

The language to have been inserted is as follows: "ASSURANCES.—The application under subsection (a)".

(The subsection formerly was subsection (b) and was redesignated as subsection (c) by section 404(b)(4) of such Public Law.)

dividuals to provide such services, which funds would (except for such grant) be made available to the applicant; and

(B) be used to supplement and, to the extent practicable, increase the level of such funds;

(2)(A) the applicant's program is in full compliance with the standards established under subsection (b), or

(B)(i) the applicant will make substantial progress toward bringing the program into compliance with such standards, and (ii) the program will, not later than three years after the date of approval of the initial application or the date standards are promulgated under subsection (b), whichever is later, fully comply with such standards;

(3) the human rights of all individuals with developmental disabilities (especially those individuals without familial protection) who are receiving services under programs assisted under this part will be protected consistent with section 110 (relating to rights of individuals with developmental disabilities);

(4) the activities conducted under this part are consistent with, and to the extent feasible, complement and further, the objectives contained in the State plan required under section 122; and

(5) before the submission of such application, an opportunity for comment has been provided to the general public and the State Developmental Disabilities Council of the State in which the program will be conducted.

(d) CONSUMER ADVISORY COMMITTEE.—The Secretary shall only make grants under section 152(a) to university affiliated programs that establish a consumer advisory committee comprised of individuals with developmental disabilities, family members of individuals with developmental disabilities, representatives of State protection and advocacy systems, State developmental disabilities councils (including State service agency directors), local agencies, and private nonprofit groups concerned with providing services for individuals with developmental disabilities, which may include representatives from parent training and information centers. The consumer advisory committee shall reflect the racial and ethnic diversity of the geographic area served by the university affiliated program.

(e) FEDERAL SHARE.—

(1) IN GENERAL.—The Federal share of any project to be provided through grants under this part may not exceed 75 percent of the necessary cost of such project, as determined by the Secretary, except that if the project activities or products target individuals with developmental disabilities who live in an urban or rural poverty area, the Federal share may not exceed 90 percent of the project's necessary costs as so determined by the Secretary.

(2) PROJECT EXPENDITURES.—For the purpose of determining the Federal share with respect to any project, expenditures on that project by a political subdivision of the State or by a public or private entity shall, subject to such limitations and conditions as the Secretary may by regulation prescribe, be

considered to be expenditures made by a university affiliated program under this part.

(f) PEER REVIEW.—

(1) IN GENERAL.—The Secretary shall require appropriate technical and qualitative peer review of applications for assistance under this part by peer review groups established under paragraph (4), including on-site visits or inspections as necessary.

(2) REGULATIONS.—Regulations promulgated under paragraph (1) shall provide that the review of the application required by such paragraph shall be conducted by groups established under paragraph (4) that are composed of non-Federal individuals who, by experience and training, are highly qualified to assess the comparative quality of applications for assistance.

(3) APPROVAL.—

(A) IN GENERAL.—The Secretary may approve an application under this part only if such application has been recommended by a peer review group that has conducted the peer review required under paragraph (1).

(B) APPLICABILITY.—This paragraph shall apply to the approval of grant applications received for fiscal year 1990 and succeeding fiscal years.

(4) ESTABLISHMENT OF PEER REVIEW GROUPS.—The Secretary, acting through the Commissioner of the Administration on Developmental Disabilities, may, notwithstanding—

(A) the provisions of title 5, United States Code, concerning appointments to the competitive service;

(B) the provisions of chapter 51, and subchapter III of chapter 53 of title 5, United States Code, concerning classification and General Schedule pay rates;

¹establish such peer review groups as are necessary to carry out this subsection, and appoint and set the rates of pay for members of such groups.

(5) WAIVERS OF APPROVAL.—The Secretary may waive the provisions of paragraph (3) concerning approval of an application if the Secretary determines that exceptional circumstances warrant such a waiver.

(g) REVIEW BY OTHER FEDERAL AGENCIES.—The Secretary shall establish such a process for the review of applications for grants under section 152(a) as will ensure, to the maximum extent feasible, that each Federal agency that provides funds for the direct support of the applicant's program reviews the application.

SEC. 154. [6064] PRIORITY FOR GRANT AWARDS.

(a) IN GENERAL.—In awarding and distributing grant funds under this part, the Secretary, subject to the availability of appropriations, shall award and distribute grant funds in accordance with the following order of priorities:

(1) EXISTING STATE UNIVERSITY AFFILIATED PROGRAMS.—First priority shall be given, with respect to the provision of

¹ Indentation is so in law. Section 404(b)(7)(E) of Public Law 103-230 (108 Stat. 326) realigned the margins of subparagraphs (A) and (B), but not of the matter after and below subparagraph (B). See clause (ii) of such section.

grant awards under section 152(a) in the amount of \$200,000, to an existing State university affiliated program that meets the requirements under section 153.

(2) **UNSERVED STATES.**—Second priority shall be given, with respect to the provision of grant awards under section 152(a) in the amount of \$200,000, to a university or public or nonprofit entity associated with a college or university that desires to establish a university affiliated program in a State that is unserved by a university affiliated program as of the date of enactment of the Developmental Assistance and Bill of Rights Act Amendments of 1994.

(3) **TRAINING PROJECTS IN ALL UNIVERSITY AFFILIATED PROGRAMS.**—Third priority shall be given, with respect to the provision of grant awards, to each university affiliated program that receives funding under section 152(a) and that meets the eligibility limitations under section 152(b) to the establishment of training projects under section 152(b) in the amount of \$90,000 in each such program.

(4) **INCREASED FUNDING FOR TRAINING PROJECTS.**—Fourth priority shall be given, with respect to the provision of grant awards, to the provision of an increase in the amount of a training project grant award under section 152(b) to \$100,000.

(5) **INCREASED FUNDING FOR UNIVERSITY AFFILIATED PROGRAMS.**—Fifth priority shall be given, with respect to the provision of grant awards, to the provision of an increase in the amount of a university affiliated program grant award under section 152(a) to \$250,000.

(6) **ADDITIONAL TRAINING.**—Sixth priority shall be given, with respect to the provision of grant awards, to an existing university affiliated program in a State that is served by such program under section 152(a) to provide additional training under subsection (b) or (c) of section 152 within such State or other geographic regions, or to a university or public or nonprofit entity associated with a college or university that desires to establish another university affiliated program within such State under section 152(a). All applications submitted to the Secretary for such grant awards shall document plans for coordinating activities with an existing university affiliated program in the State (if applicable) and in consultation with the State Developmental Disabilities Council.

(b) **ADDITIONAL PROGRAMS.**—For purposes of making grants under subsection (a)(6), the Secretary shall consider applications for grants for university affiliated programs—

(1) for States that are currently underserved by a university affiliated program; and

(2) that are in addition to the total number of university affiliated programs receiving grants under this subsection for the preceding fiscal year.

(c) **SINGLE APPLICATION.**—When every State is served by a university affiliated program under section 152(a) in the amount of \$200,000 and every such program has been awarded a training grant under section 152(b) in the amount of \$90,000, the Secretary may accept applications under such sections in a single application.

SEC. 155. [6065] DEFINITION.

For purposes of this part, the term "State" means each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, and Guam.

SEC. 156. [6066] AUTHORIZATION OF APPROPRIATIONS.

(a) **IN GENERAL.**—For the purpose of making grants under subsections (a), (b), (c), and (d) of section 152, there are authorized to be appropriated \$19,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

(b) **LIMITATION.**—With respect to peer review or other activities directly related to peer review, the Secretary may not use—

(1) for fiscal year 1994, more than \$300,000 of the funds made available under subsection (a) for such review or such other activities; and

(2) for any succeeding fiscal year, more than the amount of the funds made available under paragraph (1) adjusted to take into account the increase in the Consumer Price Index for such fiscal year for such review or such other activities.

PART E—PROJECTS OF NATIONAL SIGNIFICANCE

SEC. 161. [6081] PURPOSE.

The purpose of this part is to provide for grants and contracts for projects of national significance that support the development of national and State policy to enhance the independence, productivity, and integration and inclusion of individuals with developmental disabilities through—

(1) data collection and analysis;

(2) technical assistance to enhance the quality of State Developmental Disabilities Councils, protection and advocacy systems, and university affiliated programs; and

(3) other projects of sufficient size and scope that hold promise to expand or improve opportunities for individuals with developmental disabilities, including—

(A) technical assistance for the development of information and referral systems;

(B) educating policymakers;

(C) Federal interagency initiatives;

(D) the enhancement of participation of racial and ethnic minorities in public and private sector initiatives in developmental disabilities;

(E) transition of youth with developmental disabilities from school to adult life; and

(F) special pilots and evaluation studies to explore the expansion of programs under part B to individuals with severe disabilities other than developmental disabilities.

SEC. 162. [6082] GRANT AUTHORITY.

(a) **IN GENERAL.**—The Secretary—

(1) shall make grants to and enter into contracts with public or nonprofit private entities for projects of national signifi-

cance relating to individuals with developmental disabilities to—

(A) support ongoing data collection on expenditures, residential services and employment, and develop an ongoing data collection system, including data collection on the accomplishments of State Developmental Disabilities Councils, protection and advocacy systems, and university affiliated programs that includes data on the participation of individuals from racial and ethnic minority backgrounds; and

(B) provide technical assistance (including research, training, and evaluation) that expands or improves the effectiveness of State Developmental Disabilities Councils under part B, protection and advocacy systems under part C, and university affiliated programs under part D, including the evaluation and assessment of the quality of services provided to individuals with developmental disabilities and other activities performed by programs under parts B, C, and D; and

(2) may make grants to and enter into contracts with public or nonprofit private entities for projects of national significance relating to individuals with developmental disabilities to conduct other nationally significant initiatives of sufficient size and scope that hold promise of expanding or otherwise improving opportunities for individuals with developmental disabilities, including—

(A) conducting research and providing technical assistance to assist States to develop statewide, comprehensive information and referral and service coordination systems for individuals with developmental disabilities and their families that are culturally competent and that improve supportive living and quality of life opportunities that enhance recreation, leisure, and fitness;

(B) educating policymakers, including the training of self-advocates and family members of individuals with developmental disabilities;

(C) pursuing Federal interagency initiatives that enhance the ability of Federal agencies to address the needs of individuals with developmental disabilities and their families;

(D) expanding or otherwise improving opportunities for individuals with developmental disabilities who are from racial and ethnic minority backgrounds including projects to encourage members of such groups to participate in the Developmental Disabilities Programs authorized under parts B, C, and D, and increase the involvement of students and professionals of such groups in the provision of services to, supports to, and advocacy for, individuals with developmental disabilities; and

(E) conducting research and providing technical assistance to policymakers concerning the transition of youth with developmental disabilities from school to work and to adult life.

(b) INVESTIGATIONS.—

(1) IN GENERAL.—Not later than April 1, 1994, there shall be a special initiative to support grants to investigate the expansion of part B activities to individuals with severe disabilities other than developmental disabilities. Such investigations shall be implemented through the following activities:

(A) A national study of State Developmental Disabilities Councils that are currently mandated under State law or Executive order to focus on individuals with disabilities other than developmental disabilities. Such study shall be completed not later than June 30, 1995.

(B) Pilot initiatives by not more than five additional State Developmental Disabilities Councils, in consultation with and with the support of the protection and advocacy system and the university affiliated program in such State, to study the implications of such expansion in States in which such Councils are located and to delineate barriers, opportunities, and critical issues. Such initiatives shall be completed not later than January 1996.

(C) A national study of the process and outcomes of the pilot studies conducted under subparagraph (B). Such study shall be completed not later than May 30, 1996.

(2) APPLICATION.—No grant may be made under this subsection unless an applicant submits to the Secretary an application, and meets the additional application requirements, under subsection (c).

(c) APPLICATION AND OTHER GRANT REQUIREMENTS.—No grant may be made under subsection (a) unless—

(1) an application has been submitted to the Secretary in such form, in such manner, and containing such information as the Secretary shall by regulation prescribe and such application has been approved by the Secretary;

(2) each State in which the applicant's project will be conducted has a State plan approved under section 122;

(3) the application provides assurances that the human rights of all individuals with developmental disabilities (especially those individuals without familial protection) who are receiving services under projects assisted under this part will be protected consistent with section 110 (relating to the rights of individuals with developmental disabilities);

(4) the applicant demonstrates, where appropriate, how the project will address, in whole or part, the needs of individuals with developmental disabilities from racial and ethnic minority backgrounds; and

(5) the Secretary provides to the State Developmental Disabilities Council in such State an opportunity to review the application for such project and to submit its comments on the application.

(d) PRIORITIES FOR GRANTS.—Not later than January 1 of each year, the Secretary shall publish in the Federal Register proposed priorities for grants and contracts under this part and shall allow a period of 60 days for public comments and suggestions concerning such proposed priorities. After analyzing and considering such comments, the Secretary shall publish final priorities for such grants and contracts in the Federal Register.

(e) **GRANT PAYMENTS.**—Payments under grants under subsection (a) may be made in advance or by way of reimbursement and at such intervals and on such conditions, as the Secretary finds necessary. The amount of any grant under subsection (a) shall be determined by the Secretary, except as otherwise provided under section 163.

(f) **LIST OF RECIPIENTS.**—Not later than September 1 of each fiscal year, the Secretary shall publish in the Federal Register a list of the recipients of grants and contracts in each of the areas authorized in subsections (a) and (b), including a brief description of the project, and the amount of funds granted to each such project. The amounts for such grants and contracts shall total the amount appropriated under this part for such fiscal year.

SEC. 163. [6083] AUTHORIZATION OF APPROPRIATIONS.

(a) **IN GENERAL.**—To carry out this part, there are authorized to be appropriated \$4,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

(b) **LIMITATIONS.**—

(1) **PROJECTS OF NATIONAL SIGNIFICANCE.**—At least 8 percent, but in no event less than \$300,000, of the amounts appropriated pursuant to subsection (a) shall be used to carry out the provisions of section 162(a)(1)(B).

(2) **INVESTIGATIONS.**—

(A) **IN GENERAL.**—The additional authority to fund projects under section 162(b) shall not be construed as requiring the Secretary to supplant funding for other priorities described in this part.

(B) **TIME LINE FOR FUNDING.**—If amounts are available to carry out subparagraphs (A), (B), and (C) of section 162(b)(1), the Administration shall provide funding to carry out such subparagraphs not later than May 1 of the fiscal year in which such funds become available.

(3) **PROGRAMMATIC REVIEWS OR OTHER ADMINISTRATIVE ACTIVITIES.**—The Secretary may not use the funds made available under subsection (a) for programmatic reviews as prescribed by regulation or other administrative activities under parts B, C, and D.

(4) **TECHNICAL ASSISTANCE FOR PROTECTION AND ADVOCACY SYSTEMS.**—If technical assistance to improve the effectiveness of protection and advocacy systems under part C is provided under section 142(c)(5)—

(A) no funding for the provision of such technical assistance to protection and advocacy systems shall be provided under this part; and

(B) the amount set aside for technical assistance under section 162(a)(1)(B) shall be proportionally reduced.



MENTAL HEALTH SYSTEMS ACT

MENTAL HEALTH SYSTEMS ACT¹

(References in black brackets [] are to title 42, United States Code)

SHORT TITLE AND TABLE OF CONTENTS

SECTION 1. This Act may be cited as the "Mental Health Systems Act".

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TITLE V—MENTAL HEALTH RIGHTS AND ADVOCACY

Sec. 501. Bill of rights.

TITLE VI—RAPE PREVENTION AND CONTROL²

Sec. 601. Rape prevention and control.

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TITLE VIII—MISCELLANEOUS

* * * * *

Sec. 802. Report on shelter and basic living needs of chronically mentally ill individuals.

* * * * *

FINDINGS

SEC. 2. [9401] The Congress finds—

(1) despite the significant progress that has been made in making community mental health services available and in improving residential mental health facilities since the original community mental health centers legislation was enacted in 1963, unserved and underserved populations remain and there are certain groups in the population, such as chronically mentally ill individuals, children and youth, elderly individuals, racial and ethnic minorities, women, poor persons, and persons in rural areas, which often lack access to adequate private and public mental health services and support services;

(2) the process of transferring or diverting chronically mentally ill individuals from unwarranted or inappropriate institutionalized settings to their home communities has frequently not been accompanied by a process of providing those

¹Public Law 96-398. This compilation does not include provisions of such Public Law that amended other provisions of law.

²Section 87(d) of Public Law 99-646, and section 3(b) of Public Law 99-654, amended various provisions of this Act by striking "rape" and inserting "sex offense", but failed to conform the table of contents in the item relating to section 601.

individuals with the mental health and support services they need in community-based settings;

(3) the shift in emphasis from institutional care to community-based care has not always been accompanied by a process of affording training, retraining, and job placement for employees affected by institutional closure and conversion;

(4) the delivery of mental health and support services is typically uncoordinated within and among local, State, and Federal entities;

(5) mentally ill persons are often inadequately served by (A) programs of the Department of Health and Human Services such as medicare, medicaid, supplemental security income, and social services, and (B) programs of the Department of Housing and Urban Development, the Department of Labor, and other Federal agencies;

(6) health care systems often lack general health care personnel with adequate mental health care training and often lack mental health care personnel and consequently many individuals with some level of mental disorder do not receive appropriate mental health care;

(7) present knowledge of methods to prevent mental illness through discovery and elimination of its causes and through early detection and treatment is too limited;

(8) a comprehensive and coordinated array of appropriate private and public mental health and support services for all people in need within specific geographic areas, based upon a cooperative local-State-Federal partnership, remains the most effective and humane way to provide a majority of mentally ill individuals with mental health care and needed support; and

(9) because of the rising demand for mental health services and the wide disparity in the distribution of psychiatrists, clinical psychologists, social workers, and psychiatric nurses, there is a shortage in the medical specialty of psychiatry and there are also shortages among the other health personnel who provide mental health services.

TITLE I—GENERAL PROVISIONS

DEFINITIONS

SEC. 102. [9412] For purposes of this Act:

(1) The term "Secretary" means the Secretary of Health and Human Services.

(2) The term "State" includes (in addition to the fifty States) the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Trust Territory of the Pacific Islands, and the Northern Mariana Islands.

(3) The term "nonprofit", as applied to any entity, means an entity which is owned and operated by one or more corporations or associations no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or person.

* * * * *

TITLE V—MENTAL HEALTH RIGHTS AND ADVOCACY

BILL OF RIGHTS

SEC. 501. [9501] It is the sense of the Congress that each State should review and revise, if necessary, its laws to ensure that mental health patients receive the protection and services they require; and in making such review and revision should take into account the recommendations of the President's Commission on Mental Health and the following:

(1) A person admitted to a program or facility for the purpose of receiving mental health services should be accorded the following:

(A) The right to appropriate treatment and related services in a setting and under conditions that—

(i) are the most supportive of such person's personal liberty; and

(ii) restrict such liberty only to the extent necessary consistent with such person's treatment needs, applicable requirements of law, and applicable judicial orders.

(B) The right to an individualized, written, treatment or service plan (such plan to be developed promptly after admission of such person), the right to treatment based on such plan, the right to periodic review and reassessment of treatment and related service needs, and the right to appropriate revision of such plan, including any revision necessary to provide a description of mental health services that may be needed after such person is discharged from such program or facility.

(C) The right to ongoing participation, in a manner appropriate to such person's capabilities, in the planning of mental health services to be provided such person (including the right to participate in the development and periodic revision of the plan described in subparagraph (B)), and, in connection with such participation, the right to be provided with a reasonable explanation, in terms and language appropriate to such person's condition and ability to understand, of—

(i) such person's general mental condition and, if such program or facility has provided a physical examination, such person's general physical condition;

(ii) the objectives of treatment;

(iii) the nature and significant possible adverse effects of recommended treatments;

(iv) the reasons why a particular treatment is considered appropriate;

(v) the reasons why access to certain visitors may not be appropriate; and

(vi) any appropriate and available alternative treatments, services, and types of providers of mental health services.

(D) The right not to receive a mode or course of treatment, established pursuant to the treatment plan, in the

absence of such person's informed, voluntary, written consent to such mode or course of treatment, except treatment—

(i) during an emergency situation if such treatment is pursuant to or documented contemporaneously by the written order of a responsible mental health professional; or

(ii) as permitted under applicable law in the case of a person committed by a court to a treatment program or facility.

(E) The right not to participate in experimentation in the absence of such person's informed, voluntary, written consent, the right to appropriate protections in connection with such participation, including the right to a reasonable explanation of the procedure to be followed, the benefits to be expected, the relative advantages of alternative treatments, and the potential discomforts and risks, and the right and opportunity to revoke such consent.

(F) The right to freedom from restraint or seclusion, other than as a mode or course of treatment or restraint or seclusion during an emergency situation if such restraint or seclusion is pursuant to or documented contemporaneously by the written order of a responsible mental health professional.

(G) The right to a humane treatment environment that affords reasonable protection from harm and appropriate privacy to such person with regard to personal needs.

(H) The right to confidentiality of such person's records.

(I) The right to access, upon request, to such person's mental health care records, except such person may be refused access to—

(i) information in such records provided by a third party under assurance that such information shall remain confidential; and

(ii) specific material in such records if the health professional responsible for the mental health services concerned has made a determination in writing that such access would be detrimental to such person's health, except that such material may be made available to a similarly licensed health professional selected by such person and such health professional may, in the exercise of professional judgment, provide such person with access to any or all parts of such material or otherwise disclose the information contained in such material to such person.

(J) The right, in the case of a person admitted on a residential or inpatient care basis, to converse with others privately, to have convenient and reasonable access to the telephone and mails, and to see visitors during regularly scheduled hours, except that, if a mental health professional treating such person determines that denial of access to a particular visitor is necessary for treatment pur-

poses, such mental health professional may, for a specific, limited, and reasonable period of time, deny such access if such mental health professional has ordered such denial in writing and such order has been incorporated in the treatment plan for such person. An order denying such access should include the reasons for such denial.

(K) The right to be informed promptly at the time of admission and periodically thereafter, in language and terms appropriate to such person's condition and ability to understand, of the rights described in this section.

(L) The right to assert grievances with respect to infringement of the rights described in this section, including the right to have such grievances considered in a fair, timely, and impartial grievance procedure provided for or by the program or facility.

(M) Notwithstanding subparagraph (J), the right of access to (including the opportunities and facilities for private communication with) any available—

(i) rights protection service within the program or facility;

(ii) rights protection service within the State mental health system designed to be available to such person; and

(iii) qualified advocate;

for the purpose of receiving assistance to understand, exercise, and protect the rights described in this section and in other provisions of law.

(N) The right to exercise the rights described in this section without reprisal, including reprisal in the form of denial of any appropriate, available treatment.

(O) The right to referral as appropriate to other providers of mental health services upon discharge.

(2)(A) The rights described in this section should be in addition to and not in derogation of any other statutory or constitutional rights.

(B) The rights to confidentiality of and access to records as provided in subparagraphs (H) and (I) of paragraph (1) should remain applicable to records pertaining to a person after such person's discharge from a program or facility.

(3)(A) No otherwise eligible person should be denied admission to a program or facility for mental health services as a reprisal for the exercise of the rights described in this section.

(B) Nothing in this section should—

(i) obligate an individual mental health or health professional to administer treatment contrary to such professional's clinical judgment;

(ii) prevent any program or facility from discharging any person for whom the provision of appropriate treatment, consistent with the clinical judgment of the mental health professional primarily responsible for such person's treatment, is or has become impossible as a result of such person's refusal to consent to such treatment;

(iii) require a program or facility to admit any person who, while admitted on prior occasions to such program or facility,

has repeatedly frustrated the purposes of such admissions by withholding consent to proposed treatment; or

(iv) obligate a program or facility to provide treatment services to any person who is admitted to such program or facility solely for diagnostic or evaluative purposes.

(C) In order to assist a person admitted to a program or facility in the exercise or protection of such person's rights, such person's attorney or legal representatives should have reasonable access to—

(i) such person;

(ii) the areas of the program or facility where such person has received treatment, resided, or had access; and

(iii) pursuant to the written authorization of such person, the records and information pertaining to such person's diagnosis, treatment, and related services described in paragraph (1)(I).

(D) Each program and facility should post a notice listing and describing, in language and terms appropriate to the ability of the persons to whom such notice is addressed to understand, the rights described in this section of all persons admitted to such program or facility. Each such notice should conform to the format and content for such notices, and should be posted in all appropriate locations.

(4)(A) In the case of a person adjudicated by a court of competent jurisdiction as being incompetent to exercise the right to consent to treatment or experimentation described in subparagraph (D) or (E) of paragraph (1), or the right to confidentiality of or access to records described in subparagraph (H) or (I) of such paragraph, or to provide authorization as described in paragraph (3)(C)(iii), such right may be exercised or such authorization may be provided by the individual appointed by such court as such person's guardian or representative for the purpose of exercising such right or such authorization.

(B) In the case of a person who lacks capacity to exercise the right to consent to treatment or experimentation under subparagraph (D) or (E) of paragraph (1), or the right to confidentiality of or access to records described in subparagraph (H) or (I) of such paragraph, or to provide authorization as described in paragraph (3)(C)(iii), because such person has not attained an age considered sufficiently advanced under State law to permit the exercise of such right or such authorization to be legally binding, such right may be exercised or such authorization may be provided on behalf of such person by a parent or legal guardian of such person.

(C) Notwithstanding subparagraphs (A) and (B), in the case of a person admitted to a program or facility for the purpose of receiving mental health services, no individual employed by or receiving any remuneration from such program or facility should act as such person's guardian or representative.

TITLE VI—SEX OFFENSE PREVENTION AND CONTROL

SEX OFFENSE PREVENTION AND CONTROL

SEC. 601. [9511] (a) The Secretary, acting through the National Center for the Prevention and Control of Sex Offenses (here-

after in this section referred to as the "Center"), may, directly or by grant, carry out the following:

(1) A continuing study of sex offenses, including a study and investigation of—

(A) the effectiveness of existing Federal, State, and local laws dealing with sex offenses;

(B) the relationship, if any, between traditional legal and social attitudes toward sexual roles, sex offenses, and the formulation of laws dealing with sex offenses;

(C) the treatment of the victims of sex offenses by law enforcement agencies, hospitals or other medical institutions, prosecutors, and the courts;

(D) the causes of sex offenses, identifying to the degree possible—

(i) social conditions which encourage sexual attacks, and

(ii) the motives of offenders, and

(E) the impact of a sex offense on the victim and family of the victim;

(F) sexual assaults in correctional institutions;

(G) the estimated actual incidence of forcible sex offenses as compared to the reported incidence of forcible sex offenses and the reasons for any difference between the two; and

(H) the effectiveness of existing private and local and State government educational, counseling, and other programs designed to prevent and control sex offenses.

(2) The compilation, analysis, and publication of summaries of the continuing study conducted under paragraph (1) and the research and demonstration projects conducted under paragraph (5). The Secretary shall submit not later than March 30, 1983, to the Congress a summary of such study and projects together with a review of their effectiveness and recommendations where appropriate.

(3) The development and maintenance of an information clearinghouse with regard to—

(A) the prevention and control of sex offenses;

(B) the treatment and counseling of the victims of sex offenses and their families; and

(C) the rehabilitation of offenders.

(4) The compilation and publication of training materials for personnel who are engaged or intend to engage in programs designed to prevent and control rape.

(5) Assistance to qualified public and nonprofit private entities in conducting research and demonstration projects concerning the prevention and control of rape, including projects (A) for the planning, development, implementation, and evaluation of alternative methods used in the prevention and control of rape, the treatment and counseling of the victims of rape and their families, and the rehabilitation of offenders; (B) for the application of such alternative methods; and (C) for the promotion of community awareness of the specific locations in which, and the specific social and other conditions under which sexual attacks are most likely to occur.

(b) The Secretary shall appoint an advisory committee to advise, consult with, and make recommendations to the Secretary on the implementation of subsection (a). The recommendations of the committee shall be submitted directly to the Secretary without review or revision by any person without the consent of the committee. The Secretary shall appoint to such committee persons who are particularly qualified to assist in carrying out the functions of the committee. A majority of the members of the committee shall be women. Members of the advisory committee shall receive compensation at rates, not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule, for each day (including traveltime) they are engaged in the performance of their duties as members of the advisory committee and, while so serving away from their homes or regular places of business, each member shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as authorized by section 5703 of title 5, United States Code, for persons in Government service employed intermittently.

(c) No grant may be made under subsection (a) unless an application therefor is submitted to and approved by the Secretary. The application shall be submitted in such form and manner and contain such information as the Secretary may prescribe.

(d) For the purpose of carrying out subsection (a), there are authorized to be appropriated \$6,000,000 for the fiscal year ending September 30, 1981, \$1,500,000 for the fiscal year ending September 30, 1982, \$1,500,000 for the fiscal year ending September 30, 1983.

(e) For purposes of subsection (a), the term "sex offense" includes statutory and attempted rape and any other criminal sexual assault (whether homosexual or heterosexual) which involves force or the threat of force.

(f) Part D of the Community Mental Health Centers Act is repealed.

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TITLE VIII—MISCELLANEOUS

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REPORT ON SHELTER AND BASIC LIVING NEEDS OF CHRONICALLY MENTALLY ILL INDIVIDUALS

SEC. 802. [9522] (a) The Secretary of Health and Human Services and the Secretary of Housing and Urban Development shall jointly submit a report to the Committees on Labor and Human Resources and Banking, Housing, and Urban Affairs of the Senate, and the Committees on Interstate and Foreign Commerce and Banking, Finance and Urban Affairs of the House of Representatives, relating to Federal efforts to respond to the shelter and basic living needs of chronically mentally ill individuals.

(b) The report required by subsection (a) shall include—

(1) an analysis of the extent to which chronically mentally ill individuals remain inappropriately housed in institutional facilities or have otherwise inadequate or inappropriate housing arrangements;

(2) an analysis of available permanent noninstitutional housing arrangements for the chronically mentally ill;

(3) an evaluation of ongoing permanent and demonstration programs, funded in whole or in part by Federal funds, which are designed to provide noninstitutional shelter and basic living services for the chronically mentally ill, including—

(A) a description of each program;

(B) the total number of individuals estimated to be eligible to participate in each program, the number of individuals served by each program, and an estimate of the total population each program expects to serve; and

(C) an assessment of the effectiveness of each program in the provision of shelter and basic living services;

(4) recommendations of measures to encourage States to coordinate and link the provisions in State health plans which relate to mental health and, in particular, the shelter and basic living needs of chronically mentally ill individuals, with local and State housing plans;

(5) recommendations for Federal legislation relating to the provision of permanent residential noninstitutional housing arrangements and basic living services for chronically mentally ill individuals, including an estimate of the cost of such recommendations; and

(6) any other recommendations for Federal initiatives which, in the judgment of the Secretary of Health and Human Services and the Secretary of Housing and Urban Development, will lead to improved shelter and basic living services for chronically mentally ill individuals.

(c) The report required by subsection (a) shall be submitted to the committees referred to in subsection (a) no later than January 1, 1981.

* * * * *



**CONSUMER-PATIENT RADIATION HEALTH AND SAFETY
ACT OF 1981**



CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT OF 1981¹

(References in black brackets [] are to title 42, United States Code)

SHORT TITLE

SEC. 975. This subtitle may be cited as the "Consumer-Patient Radiation Health and Safety Act of 1981".

STATEMENT OF FINDINGS

SEC. 976. [10001] The Congress finds that—

(1) it is in the interest of public health and safety to minimize unnecessary exposure to potentially hazardous radiation due to medical and dental radiologic procedures;

(2) it is in the interest of public health and safety to have a continuing supply of adequately educated persons and appropriate accreditation and certification programs administered by State governments;

(3) the protection of the public health and safety from unnecessary exposure to potentially hazardous radiation due to medical and dental radiologic procedures and the assurance of efficacious procedures are the responsibility of State and Federal governments;

(4) persons who administer radiologic procedures, including procedures at Federal facilities, should be required to demonstrate competence by reason of education, training, and experience; and

(5) the administration of radiologic procedures and the effect on individuals of such procedures have a substantial and direct effect upon United States interstate commerce.

STATEMENT OF PURPOSE

SEC. 977. [10002] It is the purpose of this subtitle to—

(1) provide for the establishment of minimum standards by the Federal Government for the accreditation of education programs for persons who administer radiologic procedures and for the certification of such persons; and

(2) insure that medical and dental radiologic procedures are consistent with rigorous safety precautions and standards.

DEFINITIONS

SEC. 978. [10003] Unless otherwise expressly provided, for purposes of this subtitle, the term—

¹ Subtitle I of title IX of Public Law 97-35.

(1) "radiation" means ionizing and nonionizing radiation in amounts beyond normal background levels from sources such as medical and dental radiologic procedures;

(2) "radiologic procedure" means any procedure or article intended for use in—

(A) the diagnosis of disease or other medical or dental conditions in humans (including diagnostic X-rays or nuclear medicine procedures); or

(B) the cure, mitigation, treatment, or prevention of disease in humans;
that achieves its intended purpose through the emission of radiation;

(3) "radiologic equipment" means any radiation electronic product which emits or detects radiation and which is used or intended for use to—

(A) diagnose disease or other medical or dental conditions (including diagnostic X-ray equipment); or

(B) cure, mitigate, treat, or prevent disease in humans;
that achieves its intended purpose through the emission or detection of radiation;

(4) "practitioner" means any licensed doctor of medicine, osteopathy, dentistry, podiatry, or chiropractic, who prescribes radiologic procedures for other persons;

(5) "persons who administer radiologic procedures" means any person, other than a practitioner, who intentionally administers radiation to other persons for medical purposes, and includes medical radiologic technologists (including dental hygienists and assistants), radiation therapy technologists, and nuclear medicine technologists;

(6) "Secretary" means the Secretary of Health and Human Services; and

(7) "State" means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

PROMULGATION OF STANDARDS

SEC. 979. [10004] (a) Within twelve months after the date of enactment of this Act, the Secretary, in consultation with the Radiation Policy Council, the Secretary of Veterans Affairs, the Administrator of the Environmental Protection Agency, appropriate agencies of the States, and appropriate professional organizations, shall by regulation promulgate minimum standards for the accreditation of educational programs to train individuals to perform radiologic procedures. Such standards shall distinguish between programs for the education of (1) medical radiologic technologists (including radiographers), (2) dental auxiliaries (including dental hygienists and assistants), (3) radiation therapy technologists, (4) nuclear medicine technologists, and (5) such other kinds of health auxiliaries who administer radiologic procedures as the Secretary deter-

mines appropriate. Such standards shall not be applicable to educational programs for practitioners.

(b) Within twelve months after the date of enactment of this Act, the Secretary, in consultation with the Radiation Policy Council, the Secretary of Veterans Affairs, the Administrator of the Environmental Protection Agency, interested agencies of the States, and appropriate professional organizations, shall by regulation promulgate minimum standards for the certification of persons who administer radiologic procedures. Such standards shall distinguish between certification of (1) medical radiologic technologists (including radiographers), (2) dental auxiliaries (including dental hygienists and assistants), (3) radiation therapy technologists, (4) nuclear medicine technologists, and (5) such other kinds of health auxiliaries who administer radiologic procedures as the Secretary determines appropriate. Such standards shall include minimum certification criteria for individuals with regard to accredited education, practical experience, successful passage of required examinations, and such other criteria as the Secretary shall deem necessary for the adequate qualification of individuals to administer radiologic procedures. Such standards shall not apply to practitioners.

MODEL STATUTE

SEC. 980. [10005] In order to encourage the administration of accreditation and certification programs by the States, the Secretary shall prepare and transmit to the States a model statute for radiologic procedure safety. Such model statute shall provide that—

(1) it shall be unlawful in a State for individuals to perform radiologic procedures unless such individuals are certified by the State to perform such procedures; and

(2) Any educational requirements for certification of individuals to perform radiologic procedures shall be limited to educational programs accredited by the State.

COMPLIANCE

SEC. 981. [10006] (a) The Secretary shall take all actions consistent with law to effectuate the purposes of this subtitle.

(b) A State may utilize an accreditation or certification program administered by a private entity if—

(1) such State delegates the administration of the State accreditation or certification program to such private entity;

(2) such program is approved by the State; and

(3) such program is consistent with the minimum Federal standards promulgated under this subtitle for such program.

(c) Absent compliance by the States with the provisions of this subtitle within three years after the date of enactment of this Act, the Secretary shall report to the Congress recommendations for legislative changes considered necessary to assure the State's compliance with this subtitle.

(d) The Secretary shall be responsible for continued monitoring of compliance by the States with the applicable provisions of this subtitle and shall report to the Senate and the House of Representatives by January 1, 1982, and January 1 of each succeeding year

the status of the States' compliance with the purposes of this subtitle.

(e) Notwithstanding any other provision of this section, in the case of a State which has, prior to the effective date of standards and guidelines promulgated pursuant to this subtitle, established standards for the accreditation of educational programs and certification of radiologic technologists, such State shall be deemed to be in compliance with the conditions of this section unless the Secretary determines, after notice and hearing, that such State standards do not meet the minimum standards prescribed by the Secretary or are inconsistent with the purposes of this subtitle.

FEDERAL RADIATION GUIDELINES

SEC. 982. [10007] The Secretary shall, in conjunction with the Radiation Policy Council, the Secretary of Veterans Affairs, the Administrator of the Environmental Protection Agency, appropriate agencies of the States, and appropriate professional organizations, promulgate Federal radiation guidelines with respect to radiologic procedures. Such guidelines shall—

(1) determine the level of radiation exposure due to radiologic procedures which is unnecessary and specify the techniques, procedures, and methods to minimize such unnecessary exposure;

(2) provide for the elimination of the need for retakes of diagnostic radiologic procedures;

(3) provide for the elimination of unproductive screening programs;

(4) provide for the optimum diagnostic information with minimum radiologic exposure; and

(5) include the therapeutic application of radiation to individuals in the treatment of disease, including nuclear medicine applications.

APPLICABILITY TO FEDERAL AGENCIES

SEC. 983. [10008] (a) Except as provided in subsection (b), each department, agency, and instrumentality of the executive branch of the Federal Government shall comply with standards promulgated pursuant to this subtitle.

(b) The Secretary of Veterans Affairs, through the Chief Medical Director of the Department of Veterans Affairs, shall, to the maximum extent feasible consistent with the responsibilities of such Secretary and Chief Medical Director under title 38, United States Code, prescribe regulations making the standards promulgated pursuant to this subtitle applicable to the provision of radiologic procedures in facilities over which that Secretary has jurisdiction. In prescribing and implementing regulations pursuant to this subsection, the Secretary of Veterans Affairs shall consult with the Secretary in order to achieve the maximum possible coordination of the regulations, standards, and guidelines, and the implementation thereof, which the Secretary and the Secretary of Veterans Affairs prescribe under this subtitle.

**DRUG ABUSE PREVENTION, TREATMENT, AND
REHABILITATION ACT**

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DRUG ABUSE PREVENTION, TREATMENT, AND REHABILITATION ACT¹

(References in brackets [] are to title 21, United States Code)

§ 1. Short title.

This Act may be cited as the "Drug Abuse Prevention, Treatment, and Rehabilitation Act".

TITLE I—FINDINGS AND DECLARATION OF POLICY; DEFINITIONS; TERMINATION²

Sec.

- 101. Congressional findings.
- 102. Declaration of national policy.
- 103. Definitions.
- 104. Termination.

§ 101. [1101] Congressional findings.

The Congress makes the following findings:

(1) Drug abuse is rapidly increasing in the United States and now afflicts urban, suburban, and rural areas of the Nation.

(2) Drug abuse seriously impairs individual, as well as societal, health and well-being.

(3) Drug abuse, especially heroin addiction, substantially contributes to crime.

(4) The adverse impact of drug abuse inflicts increasing pain and hardship on individuals, families, and communities and undermines our institutions.

(5) Too little is known about drug abuse, especially the causes, and ways to treat and prevent drug abuse.

(6) The success of Federal drug abuse programs and activities requires a recognition that education, treatment, rehabilitation, research, training, and law enforcement efforts are interrelated.

(7) The effectiveness of efforts by State and local governments and by the Federal Government to control and treat drug abuse in the United States has been hampered by a lack of coordination among the States, between States and localities, among the Federal Government, States and localities, and throughout the Federal establishment.

(8) Control of drug abuse requires the development of a comprehensive, coordinated long-term Federal strategy that encompasses both effective law enforcement against illegal

¹Public Law 92-255.

²Section 1007(c)(1) of Public Law 100-690 repealed section 103 without making a conforming amendment to the table of sections.

drug traffic and effective health programs to rehabilitate victims of drug abuse.

(9) The increasing rate of drug abuse constitutes a serious and continuing threat to national health and welfare, requiring an immediate and effective response on the part of the Federal Government.

(10) Although the Congress observed a significant apparent reduction in the rate of increase of drug abuse during the three-year period subsequent to the date of enactment of this Act, and in certain areas of the country apparent temporary reductions in its incidence, the increase and spread of heroin consumption since 1974, and the continuing abuse of other dangerous drugs, clearly indicate the need for effective, ongoing, and highly visible Federal leadership in the formation and execution of a comprehensive, coordinated drug abuse policy.

(11) Shifts in the usage of various drugs and in the Nation's demographic composition require a Federal strategy to adjust the focus of drug abuse programs to meet new needs and priorities on a cost-effective basis.

(12) The growing extent of drug abuse indicates an urgent need for prevention and intervention programs designed to reach the general population and members of high risk populations such as youth, women, and the elderly.

(13) Effective control of drug abuse requires high-level coordination of Federal international and domestic activities relating to both supply of, and demand for, commonly abused drugs.

(14) Local governments with high concentrations of drug abuse should be actively involved in the planning and coordination of efforts to combat drug abuse.

§102. [1102] Declaration of national policy.

The Congress declares that it is the policy of the United States and the purpose of this Act to focus the comprehensive resources of the Federal Government and bring them to bear on drug abuse with the objective of significantly reducing the incidence, as well as the social and personal costs, of drug abuse in the United States, and to develop and assure the implementation of a comprehensive, coordinated, long-term Federal strategy to combat drug abuse. To reach these goals, the Congress further declares that it is the policy of the United States and the purpose of this Act to meet the problems of drug abuse through—

(1) comprehensive Federal, State, and local planning for, and effective use of, Federal assistance to States and to community-based programs to meet the urgent needs of special populations, in coordination with all other governmental and nongovernmental sources of assistance;

(2) the development and support of community-based prevention programs;

(3) the development and encouragement of effective occupational prevention and treatment programs within the Government and in cooperation with the private sector; and

(4) increased Federal commitment to research into the behavioral and biomedical etiology of, the treatment of, and the

mental and physical health and social and economic consequences of, drug abuse.

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TITLE II—OFFICE OF DRUG ABUSE POLICY

Sec.

- 201. Concentration of Federal effort.¹
- 202. Designated drug representative.
- 203. Officers and employees.
- 204. Acceptance of uncompensated services.
- 205. Notice relating to the control of dangerous drugs.¹
- 206. Statutory authority unaffected.

§ 201. [1115] Notice relating to the control of dangerous drugs.

Whenever the Attorney General determines that there is evidence that—

(1) a drug or other substance, which is not a controlled substance (as defined in section 102(6) of the Controlled Substances Act), has a potential for abuse, or

(2) a controlled substance should be transferred or removed from a schedule under section 202 of such Act,

he shall, prior to initiating any proceeding under section 201(a) of such Act, give the President timely notice of such determination. Information forwarded to the Attorney General pursuant to section 201(f) of such Act shall also be forwarded by the Secretary of Health and Human Services to the President.

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TITLE IV—OTHER FEDERAL PROGRAMS²

Sec.

- 401. Community mental health centers.
- 402. Public Health Service facilities.
- 403. State plan requirements.
- 404. Drug abuse prevention function appropriations.
- 405. Special reports by the Secretary of Health and Human Services.
- 406. Additional drug abuse prevention functions of the Secretary of Health and Human Services.
- 407. Admission of drug abusers to private and public hospitals.
- 408. Confidentiality of patient records.
- 409. Repealed.
- 410. Grants and contracts for the demonstration of new and more effective prevention, treatment, and rehabilitation programs.
- 411. Records and audit.
- 412. National Drug Abuse Training Center.
- 413. Drug abuse among government and other employees.
- 414. Contract authority.

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¹Section 1007(c)(1) of Public Law 100-690 repealed sections 201, 202, 203, 204, and 206, and redesignated section 205 as section 201, without making conforming amendments to the table of sections.

²Various public laws have amended title IV without conforming the table of sections.

§ 404. [1171] Drug abuse prevention function appropriations.

Any request for appropriations by a department or agency of the Government submitted after the date of enactment of this Act shall specify (1) on a line item basis, that part of the appropriations which the department or agency is requesting to carry out its drug abuse prevention functions, and (2) the authorization of the appropriations requested to carry out each of its drug abuse prevention functions.

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§ 406. [1173] Additional drug abuse prevention functions of the Secretary of Health and Human Services.

(b) After December 31, 1974, the Secretary shall carry out his functions under subsection (a) through the National Institute on Drug Abuse.

* * * * *

§ 410. [1177] Grants and contracts for the demonstration of new and more effective prevention, treatment, and rehabilitation programs.

(a) The Secretary¹ acting through the National Institute on Drug Abuse, may make grants to and enter into contracts with individuals and public and private nonprofit entities—

(1) to provide training seminars, educational programs, and technical assistance for the development, demonstration, and evaluation of drug abuse prevention, treatment, and rehabilitation programs; and

(2) to conduct demonstration and evaluation projects, with a high priority on prevention and early intervention projects and on identifying new and more effective drug abuse prevention, treatment, and rehabilitation programs.

In the implementation of his authority under this section, the Secretary shall accord a high priority to applications for grants or contracts for primary prevention programs. For purposes of the preceding sentence, primary prevention programs include programs designed to discourage persons from beginning drug abuse. To the extent that appropriations authorized under this section are used to fund treatment services, the Secretary shall not limit such funding to treatment for opiate abuse, but shall also provide support for treatment for nonopiate drug abuse including polydrug abuse. Furthermore, nothing shall prevent the use of funds provided under this section for programs and projects aimed at the prevention, treatment, and rehabilitation of alcohol abuse and alcoholism as well as drug abuse.

(b) There are authorized to be appropriated \$25,000,000 for the fiscal year ending June 30, 1972; \$65,000,000 for the fiscal year ending June 30, 1973; \$100,000,000 for the fiscal year ending June 30, 1974; \$160,000,000 for each of the fiscal years ending June 30, 1975 and June 30, 1976; \$40,000,000 for the period July 1, 1976,

¹ So in original. "Secretary" probably should be followed by a comma.

through September 30, 1976; and \$160,000,000 for each of the fiscal years ending September 30, 1977, and September 30, 1978, to carry out this section. For the fiscal year ending September 30, 1979, there is authorized to be appropriated (1) \$153,000,000 for grants and contracts under paragraphs (3) and (6) of subsection (a) for drug abuse treatment programs, and (2) \$24,000,000 for grants and contracts under such subsection for other programs and activities. For grants and contracts under paragraphs (3) and (6) of subsection (a) for drug abuse treatment programs there is authorized to be appropriated \$149,000,000 for the fiscal year ending September 30, 1980, and \$155,000,000 for the fiscal year ending September 30, 1981; and for grants and contracts under such subsection for other programs and activities there is authorized to be appropriated \$20,000,000 for the fiscal year ending September 30, 1980, and \$30,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under the preceding sentence for the fiscal year ending September 30, 1980, at least 7 percent of the funds shall be obligated for grants and contracts for primary prevention and intervention programs designed to discourage individuals, particularly those in high risk populations, from abusing drugs; and of the funds appropriated under the preceding sentence for the next fiscal year, at least 10 percent of the funds shall be obligated for such grants and contracts. For carrying out the purposes of this section, there are authorized to be appropriated \$15,000,000 for the fiscal year ending September 30, 1982. Of the funds appropriated under the preceding sentence, at least 25 per centum of the funds shall be obligated for grants and contracts for primary prevention and intervention programs designed to discourage individuals, particularly individuals in high risk populations, from abusing drugs.

(c)(1) In carrying out this section, the Secretary shall require coordination of all applications for programs in a State and shall not give precedence to public agencies over private agencies, institutions, and organizations, or to State agencies over local agencies.

(2) Each applicant within a State, upon filing its application with the Secretary for a grant or contract under this section, shall submit a copy of its application for review by the State agency (if any) responsible for the administration of drug abuse prevention activities. Such State agency shall be given not more than thirty days from the date of receipt of the application to submit to the Secretary, in writing, an evaluation of the project set forth in the application. Such evaluation shall include comments on the relationship of the project to other projects pending and approved and to any State comprehensive plan for treatment and prevention of drug abuse. The State shall furnish the applicant a copy of any such evaluation. A State if it so desires may, in writing, waive its rights under this paragraph.

(3) Approval of any application for a grant or contract under this section by the Secretary, including the earmarking of financial assistance for a program or project, may be granted only if the application substantially meets a set of criteria that

(A) provide that the activities and services for which assistance under this section is sought will be substantially administered by or under the supervision of the applicant;

(B) provide for such methods of administration as are necessary for the proper and efficient operation of such programs or projects; and

(C) provide for such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for Federal funds paid to the applicant.

(4) Each applicant within a State, upon filing its application with the Secretary for a grant or contract to provide treatment or rehabilitation services shall provide a proposed performance standard or standards, to measure, or research protocol to determine, the effectiveness of such treatment or rehabilitation program or project.

(d) The Secretary shall encourage the submission of and give special consideration to applications under this section to programs and projects aimed at underserved populations such as racial and ethnic minorities, Native Americans (including Native Hawaiians and Native American Pacific Islanders, youth, the elderly, women, handicapped individuals, and families of drug abusers.

(e) Payment under grants or contracts under this section may be made in advance or by way of reimbursement and in such installments as the Secretary may determine.

(f) Projects and programs for which grants and contracts are made or entered into under this section shall, in the case of prevention and treatment services, seek to (1) be responsive to special requirements of handicapped individuals in receiving such services; (2) whenever possible, be community based, insure care of good quality in general community care facilities and under health insurance plans, and be integrated with, and provide for the active participation of, a wide range of public and nongovernmental agencies, organizations, institutions, and individuals; (3) where a substantial number of the individuals in the population served by the project or program are of limited English-speaking ability (A) utilize the services of outreach workers fluent in the language spoken by a predominant number of such individuals and develop a plan and make arrangements responsive to the needs of such population for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and (B) identify an individual who is fluent both in that language and English and whose responsibilities shall include providing guidance to the individuals of limited English speaking ability and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences; and (4) where appropriate, utilize existing community resources (including community mental health centers).

(g)(1) No grant may be made under this section to a State or to any entity within the government of a State unless the grant application has been duly authorized by the chief executive officer of such State.

(2) No grant or contract may be made under this section for a period in excess of five years.

(3)(A) The amount of any grant or contract under this section may not exceed 100 per centum of the cost of carrying out the grant or contract in the first fiscal year for which the grant or contract is made under this section, 80 per centum of such cost in the

second fiscal year for which the grant or contract is made under this section, 70 per centum of such cost in the third fiscal year for which the grant or contract is made under this section, and 60 per centum of such cost in each of the fourth and fifth fiscal years for which the grant or contract is made under this section.

(B) For purposes of this paragraph, no grant or contract shall be considered to have been made under this section for a fiscal year ending before September 30, 1981.

§ 411. [1178] Records and audit.

(a) Each recipient of assistance under section 410 pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant or contract, the total cost of the project or undertaking in connection with which such grant or contract is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(b) The Secretary and Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to such grants or contracts.

§ 412. [1179] National Drug Abuse Training Center.

(a) The Director shall establish a National Drug Abuse Training Center (hereinafter in this section referred to as the "Center") to develop, conduct, and support a full range of training programs relating to drug abuse prevention functions. The Director shall consult with the National Advisory Council for Drug Abuse Prevention regarding the general policies of the Center. The Director may supervise the operation of the Center initially, but shall transfer the supervision of the operation of the Center to the National Institute on Drug Abuse not later than December 31, 1974.

(b) The Center shall conduct or arrange for training programs, seminars, meetings, conferences, and other related activities, including the furnishing of training and educational materials for use by others.

(c) The services and facilities of the Center shall, in accordance with regulations prescribed by the Director, be available to (1) Federal, State, and local government officials, and their respective staffs, (2) medical and paramedical personnel, and educators, and (3) other persons, including drug dependent persons, requiring training or education in drug abuse prevention.

(d)(1) For the purpose of carrying out this section, there are authorized to be appropriated \$1,000,000 for the fiscal year ending June 30, 1972, \$3,000,000 for the fiscal year ending June 30, 1973, \$5,000,000 for the fiscal year ending June 30, 1974, and \$6,000,000 for the fiscal year ending June 30, 1975.

(2) Sums appropriated under this subsection shall remain available for obligation or expenditure in the fiscal year for which appropriated and in the fiscal year next following.

§ 414. [1181] Contract authority.

The authority of the Secretary to enter into contracts under this title and title V shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

**PROTECTION AND ADVOCACY FOR MENTALLY ILL
INDIVIDUALS ACT OF 1986**



PROTECTION AND ADVOCACY FOR MENTALLY ILL INDIVIDUALS ACT OF 1986¹

(References in brackets [] are to title 42, United States Code)

TITLE I—PROTECTION AND ADVOCACY SYSTEMS²

PART A—ESTABLISHMENT OF SYSTEMS

FINDINGS AND PURPOSE

SEC. 101. [10801] (a) The Congress finds that—

(1) individuals with mental illness are vulnerable to abuse and serious injury;

(2) family members of individuals with mental illness play a crucial role in being advocates for the rights of individuals with mental illness where the individuals are minors, the individuals are legally competent and choose to involve the family members, and the individuals are legally incompetent and the legal guardians, conservators, or other legal representatives are members of the family;

(3) individuals with mental illness are subject to neglect, including lack of treatment, adequate nutrition, clothing, health care, and adequate discharge planning; and

(4) State systems for monitoring compliance with respect to the rights of individuals with mental illness vary widely and are frequently inadequate.

(b) The purposes of this Act are—

(1) to ensure that the rights of individuals with mental illness are protected; and

(2) to assist States to establish and operate a protection and advocacy system for individuals with mental illness which will—

(A) protect and advocate the rights of such individuals through activities to ensure the enforcement of the Constitution and Federal and State statutes; and

(B) investigate incidents of abuse and neglect of individuals with mental illness if the incidents are reported to the system or if there is probable cause to believe that the incidents occurred.

DEFINITIONS

SEC. 102. [10802] For purposes of this title:

¹Public Law 99-319. The first section of that Public Law provides as follows: "That this Act may be cited as the 'Protection and Advocacy for Mentally Ill Individuals Act of 1986'."

²References in this Act to "a individual with mental illness" probably should be "an individual with mental illness". Section 10(1) of Public Law 102-173 (105 Stat. 1219) replaced the term "mentally ill individual" with the term "individual with mental illness".

(1) The term "abuse" means any act or failure to act by an employee of a facility rendering care or treatment which was performed, or which was failed to be performed, knowingly, recklessly, or intentionally, and which caused, or may have caused, injury or death to a individual with mental illness, and includes acts such as—

(A) the rape or sexual assault of a individual with mental illness;

(B) the striking of a individual with mental illness;

(C) the use of excessive force when placing a individual with mental illness in bodily restraints; and

(D) the use of bodily or chemical restraints on a individual with mental illness which is not in compliance with Federal and State laws and regulations.

(2) The term "eligible system" means the system established in a State to protect and advocate the rights of persons with developmental disabilities under part C of the Developmental Disabilities Assistance and Bill of Rights Act.

(3) The term "facilities" may include, but need not be limited to, hospitals, nursing homes, community facilities for individuals with mental illness, board and care homes, homeless shelters, and jails and prisons.

(4) The term "individual with mental illness" means an individual—

(A) who has a significant mental illness or emotional impairment, as determined by a mental health professional qualified under the laws and regulations of the State; and

(B)(i) who is an inpatient or resident in a facility rendering care or treatment, even if the whereabouts of such inpatient or resident are unknown;

(ii) who is in the process of being admitted to a facility rendering care or treatment, including persons being transported to such a facility; or¹;

(iii) who is involuntarily confined in a municipal detention facility for reasons other than serving a sentence resulting from conviction for a criminal offense.

(5) The term "neglect" means a negligent act or omission by any individual responsible for providing services in a facility rendering care or treatment which caused or may have caused injury or death to a individual with mental illness or which placed a individual with mental illness at risk of injury or death, and includes an act or omission such as the failure to establish or carry out an appropriate individual program plan or treatment plan for a individual with mental illness, the failure to provide adequate nutrition, clothing, or health care to a individual with mental illness, or the failure to provide a safe environment for a individual with mental illness, including the failure to maintain adequate numbers of appropriately trained staff.

(6) The term "Secretary" means the Secretary of Health and Human Services.

¹So in original. See section 3(2)(C) of Public Law 100-509.

(7) The term "State" means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, American Samoa, the Virgin Islands, and the Trust Territory of the Pacific Islands.

ALLOTMENTS

SEC. 103. [10803] The Secretary shall make allotments under this title to eligible systems to establish and administer systems—

(1) which meet the requirements of section 105; and

(2) which are designed to—

(A) protect and advocate the rights of individuals with mental illness; and

(B) investigate incidents of abuse and neglect of individuals with mental illness if the incidents are reported to the system or if there is probable cause to believe that the incidents occurred.

USE OF ALLOTMENTS

SEC. 104. [10804] (a)(1) An eligible system may use its allotment under this title to enter into contracts with State agencies and nonprofit organizations which operate throughout the State. In order to be eligible for a contract under this paragraph—

(A) such an agency shall be independent of any agency which provides treatment or services (other than advocacy services) to individuals with mental illness; and

(B) such an agency or organization shall have the capacity to protect and advocate the rights of individuals with mental illness.

(2) In carrying out paragraph (1), an eligible system should consider entering into contracts with organizations including, in particular, groups run by individuals who have received or are receiving mental health services, or the family members of such individuals, which, provide protection or advocacy services to individuals with mental illness.

(b)(1) If an eligible system is a public entity, the government of the State in which the system is located may not require the system to obligate more than 5 percent of its allotment under this title in any fiscal year for administrative expenses.

(2) An eligible system may not use more than 10 percent of any allotment under this title for any fiscal year for the costs of providing technical assistance and training to carry out this title.

(c) An eligible system may use its allotment under this title to provide representation to individuals with mental illness in Federal facilities who request representation by the eligible system. Representatives of such individuals from such system shall be accorded all the rights and authority accorded to other representatives of residents of such facilities pursuant to State law and other Federal laws.

SYSTEM REQUIREMENTS

SEC. 105. [10805] (a) A system established in a State under section 103 to protect and advocate the rights of individuals with mental illness shall—

(1) have the authority to—

(A) investigate incidents of abuse and neglect of individuals with mental illness if the incidents are reported to the system or if there is probable cause to believe that the incidents occurred;

(B) pursue administrative, legal, and other appropriate remedies to ensure the protection of individuals with mental illness who are receiving care or treatment in the State; and

(C) pursue administrative, legal, and other remedies on behalf of an individual who—

(i) was a individual with mental illness; and

(ii) is a resident of the State,

but only with respect to matters which occur within 90 days after the date of the discharge of such individual from a facility providing care or treatment;

(2) be independent of any agency in the State which provides treatment or services (other than advocacy services) to individuals with mental illness;

(3) have access to facilities in the State providing care or treatment;

(4) in accordance with section 106, have access to all records of—

(A) any individual who is a client of the system if such individual, or the legal guardian, conservator, or other legal representative of such individual, has authorized the system to have such access;

(B) any individual (including an individual who has died or whose whereabouts are unknown)—

(i) who by reason of the mental or physical condition of such individual is unable to authorize the system to have such access;

(ii) who does not have a legal guardian, conservator, or other legal representative, or for whom the legal guardian is the State; and

(iii) with respect to whom a complaint has been received by the system or with respect to whom as a result of monitoring or other activities (either of which result from a complaint or other evidence) there is probable cause to believe that such individual has been subject to abuse or neglect; and

(C) any individual with a mental illness, who has a legal guardian, conservator, or other legal representative, with respect to whom a complaint has been received by the system or with respect to whom there is probable cause to believe the health or safety of the individual is in serious and immediate jeopardy, whenever—

(i) such representative has been contacted by such system upon receipt of the name and address of such representative;

(ii) such system has offered assistance to such representative to resolve the situation; and

(iii) such representative has failed or refused to act on behalf of the individual;

(5) have an arrangement with the Secretary and the agency of the State which administers the State plan under title XIX of the Social Security Act for the furnishing of the information required by subsection (b);

(6) establish an advisory council—

(A) which will advise the system on policies and priorities to be carried out in protecting and advocating the rights of individuals with mental illness;

(B) which shall include attorneys, mental health professionals, individuals from the public who are knowledgeable about mental illness, a provider of mental health services, individuals who have received or are receiving mental health services, and family members of such individuals, and at least 60 percent the membership of which shall be comprised of individuals who have received or are receiving mental health services or who are family members of such individuals; and

(C) which shall be chaired by an individual who has received or is receiving mental health services or who is a family member of such an individual;

(7) on January 1, 1987, and January 1 of each succeeding year, prepare and transmit to the Secretary and the head of the State mental health agency of the State in which the system is located a report describing the activities, accomplishments, and expenditures of the system during the most recently completed fiscal year, including a section prepared by the advisory council that describes the activities of the council and its assessment of the operations of the system;

(8) on an annual basis, provide the public with an opportunity to comment on the priorities established by, and the activities of, the system; and

(9) establish a grievance procedure for clients or prospective clients of the system to assure that individuals with mental illness have full access to the services of the system and for individuals who have received or are receiving mental health services, family members of such individuals with mental illness, or representatives of such individuals or family members to assure that the eligible system is operating in compliance with the provisions of this title and title III.

(b) The Secretary and the agency of a State which administers its State plan under title XIX of the Social Security Act shall provide the eligible system of the State with a copy of each annual survey report and plan of corrections for cited deficiencies made pursuant to titles XVIII and XIX of the Social Security Act with respect to any facility rendering care or treatment to individuals with mental illness in the State in which such system is located. A re-

port or plan shall be made available within 30 days after the completion of the report or plan.

(c)(1)(A) Each system established in a State, through allotments received under section 103, to protect and advocate the rights of individuals with mental illness shall have a governing authority.

(B) In States in which the governing authority is organized as a private non-profit entity with a multi-member governing board, or a public system with a multi-member governing board, such governing board shall be selected according to the policies and procedures of the system. The governing board shall be composed of—

(i) members (to be selected no later than October 1, 1990) who broadly represent or are knowledgeable about the needs of the clients served by the system; and

(ii) in the case of a governing authority organized as a private non-profit entity, members who broadly represent or are knowledgeable about the needs of the clients served by the system including the chairperson of the advisory council of such system. As used in this subparagraph, the term "members who broadly represent or are knowledgeable about the needs of the clients served by the system" shall be construed to include individuals who have received or are receiving mental health services and family members of such individuals.¹

(2) The governing authority established under paragraph (1) shall—

(A) be responsible for the planning, design, implementation, and functioning of the system; and

(B) consistent with subparagraph (A), jointly develop the annual priorities of the system with the advisory council.

ACCESS TO RECORDS

SEC. 106. [10806] (a) An eligible system which, pursuant to section 105(a)(4), has access to records which, under Federal or State law, are required to be maintained in a confidential manner by a provider of mental health services, shall, except as provided in subsection (b), maintain the confidentiality of such records to the same extent as is required of the provider of such services.

(b)(1) Except as provided in paragraph (2), an eligible system which has access to records pursuant to section 105(a)(4) may not disclose information from such records to the individual who is the subject of the information if the mental health professional responsible for supervising the provision of mental health services to such individual has provided the system with a written determination that disclosure of such information to such individual would be detrimental to such individual's health.

(2)(A) If disclosure of information has been denied under paragraph (1) to an individual—

(i) such individual;

(ii) the legal guardian, conservator, or other legal representative of such individual; or

¹So in original. Section 6(d) of Public Law 102-173 (105 Stat. 1218) amended subparagraph (B) by adding the above sentence at the end.

(iii) an eligible system, acting on behalf of an individual described in subparagraph (B), may select another mental health professional to review such information and to determine if disclosure of such information would be detrimental to such individual's health. If such mental health professional determines, based on professional judgment, that disclosure of such information would not be detrimental to the health of such individual, the system may disclose such information to such individual.

(B) An eligible system may select a mental health professional under subparagraph (A)(iii) on behalf of—

(i) an individual whose legal guardian is the State; or

(ii) an individual who has a legal guardian, conservator, or other legal representative other than the State if such guardian, conservator, or representative does not, within a reasonable time after such individual is denied access to information under paragraph (1), select a mental health professional under subparagraph (A) to review such information.

(C) If the laws of a State prohibit an eligible system from obtaining access to the records of individuals with mental illness in accordance with section 105(a)(4) and this section, section 105(a)(4) and this section shall not apply to such system before—

(i) the date such system is no longer subject to such a prohibition; or

(ii) the expiration of the 2-year period beginning on the date of the enactment of this Act, whichever occurs first.

(3)(A) As used in this section, the term "records" includes reports prepared by any staff of a facility rendering care and treatment or reports prepared by an agency charged with investigating reports of incidents of abuse, neglect, and injury occurring at such facility that describe incidents of abuse, neglect, and injury occurring at such facility and the steps taken to investigate such incidents, and discharge planning records.

(B) An eligible system shall have access to the type of records described in subparagraph (A) in accordance with the provisions of subsection (a) and paragraphs (1) and (2) of subsection (b).

LEGAL ACTIONS

SEC. 107. [10807] (a) Prior to instituting any legal action in a Federal or State court on behalf of a individual with mental illness, an eligible system, or a State agency or nonprofit organization which entered into a contract with an eligible system under section 104(a), shall exhaust in a timely manner all administrative remedies where appropriate. If, in pursuing administrative remedies, the system, agency, or organization determines that any matter with respect to such individual will not be resolved within a reasonable time, the system, agency, or organization may pursue alternative remedies, including the initiation of a legal action.

(b) Subsection (a) does not apply to any legal action instituted to prevent or eliminate imminent serious harm to a individual with mental illness.

PART B—ADMINISTRATIVE PROVISIONS

APPLICATIONS

SEC. 111. [10821] (a) No allotment may be made under this title to an eligible system unless an application therefor is submitted to the Secretary. Each such application shall contain—

(1) assurances that amounts paid to such system from an allotment under this title will be used to supplement and not to supplant the level of non-Federal funds available in the State in which such system is established to protect and advocate the rights of individuals with mental illness;

(2) assurances that such system will have a staff which is trained or being trained to provide advocacy services to individuals with mental illness and to work with family members of clients served by the system where the individuals with mental illness are minors, legally competent and do not object, and legally incompetent and the legal guardians, conservators, or other legal representatives are family members;

(3) assurances that such system, and any State agency or nonprofit organization with which such system may enter into a contract under section 104(a), will not, in the case of any individual who has a legal guardian, conservator, or representative other than the State, take actions which are duplicative of actions taken on behalf of such individual by such guardian, conservator, or representative unless such guardian, conservator, or representative requests the assistance of such system; and

(4) such other information as the Secretary may by regulation prescribe.

(b) The assurance required under subsection (a)(2) regarding trained staff may be satisfied through the provision of training by individuals who have received or are receiving mental health services and family members of such individuals.

(c) Applications submitted under this section shall remain in effect for a 4-year period, and the assurances required under this section shall be for the same 4-year period.

ALLOTMENT FORMULA AND REALLOTMENTS

SEC. 112. [10822] (a)(1)(A) Except as provided in paragraph (2) and subject to the availability of appropriations under section 117, the Secretary shall make allotments under section 103 from amounts appropriated under section 117 for a fiscal year to eligible systems on the basis of a formula prescribed by the Secretary which is based equally—

(i) on the population of each State in which there is an eligible system; and

(ii) on the population of each such State weighted by its relative per capita income.

(B) For purposes of subparagraph (A)(ii), the term “relative per capita income” means the quotient of the per capita income of the United States and the per capita income of the State, except that if the State is Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Trust Territory of the Pacific Is-

lands, or the Virgin Islands, the quotient shall be considered to be one.

(2) Notwithstanding paragraph (1) and subject to the availability of appropriations under section 117—

(A) if the total amount appropriated in a fiscal year is at least \$13,000,000—

(i) the amount of the allotment of the eligible system of each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico shall be the greater of—

(I) \$140,000; or

(II) \$125,000 in addition to the amount determined under paragraph (3); and

(ii) the amount of the allotment of the eligible system of Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and the Virgin Islands shall be the greater of—

(I) \$75,000; or

(II) \$67,000 in addition to the amount determined under paragraph (3); and

(B) if the total amount appropriated in a fiscal year is less than \$13,000,000, the amount of the allotment of the eligible system—

(i) of each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico shall not be less than \$125,000 in addition to the amount determined under paragraph (3); and

(ii) of Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and the Virgin Islands shall not be less than \$67,000 in addition to the amount determined under paragraph (3).

(3) In any case in which the total amount appropriated under section 117 for a fiscal year exceeds the total amount appropriated under such section, as in effect on the day before the date of enactment of this paragraph, for the preceding fiscal year by a percentage greater than the most recent percentage change in the Consumer Price Index published by the Secretary of Labor under section 100(c)(1) of the Rehabilitation Act of 1973, the Secretary shall increase each of the allotments under clauses (i)(II) and (ii)(II) of subparagraph (A) and clauses (i) and (ii) of subparagraph (B) of paragraph (2) by an amount which bears the same ratio to the amount of such minimum allotment (including any increases in such minimum allotment under this paragraph for prior fiscal years) as the amount which is equal to the difference between—

(A) the total amount appropriated under section 117 for the fiscal year for which the increase in minimum allotment is made, minus;

(B) the total amount appropriated under section 117 for the immediately preceding fiscal year, bears to the total amount appropriated under section 117 for such preceding fiscal year.

(b)(1) To the extent that all the amounts appropriated under section 117 for a fiscal year are not allotted to eligible systems because—

(A) one or more eligible systems have not submitted an application for an allotment for such fiscal year; or

(B) one or more eligible systems have notified the Secretary that they do not intend to use the full amount of their allotment,

the amount which is not so allotted shall be reallocated among the remaining eligible systems.

(2) The amount of an allotment to an eligible system for a fiscal year which the Secretary determines will not be required by the system during the period for which it is available shall be available for reallocation by the Secretary to other eligible systems with respect to which such a determination has not been made.

(3) The Secretary shall make reallocations under paragraphs (1) and (2) on such date or dates as the Secretary may fix (but not earlier than 30 days after the Secretary has published notice of the intention of the Secretary to make such reallocation in the Federal Register). A reallocation to an eligible system shall be made in proportion to the original allotment of such system for such fiscal year, but with such proportionate amount for such system being reduced to the extent it exceeds the sum the Secretary estimates such system needs and will be able to use during such period. The total of such reductions shall be similarly reallocated among eligible systems whose proportionate amounts were not so reduced. Any amount so reallocated to an eligible system for a fiscal year shall be deemed to be a part of its allotment under subsection (a) for such fiscal year.

PAYMENTS UNDER ALLOTMENTS

SEC. 113. [10823] For each fiscal year, the Secretary shall make payments to each eligible system from its allotment under this title. Any amount paid to an eligible system for a fiscal year and remaining unobligated at the end of such year shall remain available to such system for the next fiscal year for the purposes for which it was made.

REPORTS BY THE SECRETARY

SEC. 114. [10824] (a) The Secretary shall include in each report required under section 107(c) of the Developmental Disabilities Assistance and Bill of Rights Act a separate statement which contains—

(1) a description of the activities, accomplishments, and expenditures of systems to protect and advocate the rights of individuals with mental illness supported with payments from allotments under this title, including—

(A) a specification of the total number of individuals with mental illness served by such systems;

(B) a description of the types of activities undertaken by such systems;

(C) a description of the types of facilities providing care or treatment with respect to which such activities are undertaken;

(D) a description of the manner in which such activities are initiated; and

(E) a description of the accomplishments resulting from such activities;

(2) a description of—

(A) systems to protect and advocate the rights of individuals with mental illness supported with payments from allotments under this title;

(B) activities conducted by States to protect and advocate such rights;

(C) mechanisms established by residential facilities for individuals with mental illness to protect and advocate such rights; and

(D) the coordination among such systems, activities, and mechanisms;

(3) a specification of the number of systems established with allotments under this title and of whether each such system was established by a public or nonprofit private entity; and

(4) recommendations for activities and services to improve the protection and advocacy of the rights of individuals with mental illness and a description of needs for such activities and services which have not been met by systems established under this title.

(b) In preparing each statement required by subsection (a), the Secretary shall use and include information submitted to the Secretary in the reports required under section 105(a)(7).

TECHNICAL ASSISTANCE

SEC. 115.¹ [10825] The Secretary shall use not more than 2 percent of the amounts appropriated under section 117 to provide technical assistance to eligible systems with respect to activities carried out under this title, consistent with requests by such systems for such assistance.

ADMINISTRATION

SEC. 116. [10826] (a) IN GENERAL.—The Secretary shall carry out this title through the Administrator of the Substance Abuse and Mental Health Services Administration.

(b) REGULATIONS.—Not later than 6 months after the date of enactment of this subsection, the Secretary shall promulgate final regulations to carry out this title and title III.

SEC. 117. [10827] AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated for allotments under this title, \$19,500,000 for fiscal year 1992, and such sums as may be necessary for each of the fiscal years 1993 through 1995.

¹ Section 7(b)(2) of Public Law 100-509 provided that “[s]ection 10 (42 U.S.C. 10825) is amended to read as follows”. The Act does not contain a section 10; however, the citation provided for the United States Code was the correct citation for section 115, and the language added by the amendment designated the language as section “115”. The amendment has been executed to effectuate the probable intent of the Congress.

TITLE II—RESTATEMENT OF BILL OF RIGHTS FOR MENTAL HEALTH PATIENTS

RESTATEMENT OF BILL OF RIGHTS

SEC. 201. [10841] It is the sense of the Congress that, as previously stated in title V of the Mental Health Systems Act, each State should review and revise, if necessary, its laws to ensure that mental health patients receive the protection and services they require, and that in making such review and revision, States should take into account the recommendations of the President's Commission on Mental Health and the following:

(1) A person admitted to a program or facility for the purpose of receiving mental health services should be accorded the following:

(A) The right to appropriate treatment and related services in a setting and under conditions that—

(i) are the most supportive of such person's personal liberty; and

(ii) restrict such liberty only to the extent necessary consistent with such person's treatment needs, applicable requirements of law, and applicable judicial orders.

(B) The right to an individualized, written, treatment or service plan (such plan to be developed promptly after admission of such person), the right to treatment based on such plan, the right to periodic review and reassessment of treatment and related service needs, and the right to appropriate revision of such plan, including any revision necessary to provide a description of mental health services that may be needed after such person is discharged from such program or facility.

(C) The right to ongoing participation, in a manner appropriate to such person's capabilities, in the planning of mental health services to be provided such person (including the right to participate in the development and periodic revision of the plan described in subparagraph (B)), and, in connection with such participation, the right to be provided with a reasonable explanation, in terms and language appropriate to such person's condition and ability to understand, of—

(i) such person's general mental condition and, if such program or facility has provided a physical examination, such person's general physical condition;

(ii) the objectives of treatment;

(iii) the nature and significant possible adverse effects of recommended treatments;

(iv) the reasons why a particular treatment is considered appropriate;

(v) the reasons why access to certain visitors may not be appropriate; and

(vi) any appropriate and available alternative treatments, services, and types of providers of mental health services.

(D) The right not to receive a mode or course of treatment, established pursuant to the treatment plan, in the absence of such person's informed, voluntary, written consent to such mode or course of treatment, except treatment—

(i) during an emergency situation if such treatment is pursuant to or documented contemporaneously by the written order of a responsible mental health professional; or

(ii) as permitted under applicable law in the case of a person committed by a court to a treatment program or facility.

(E) The right not to participate in experimentation in the absence of such person's informed, voluntary, written consent, the right to appropriate protections in connection with such participation, including the right to a reasonable explanation of the procedure to be followed, the benefits to be expected, the relative advantages of alternative treatments, and the potential discomforts and risks, and the right and opportunity to revoke such consent.

(F) The right to freedom from restraint or seclusion, other than as a mode or course of treatment or restraint or seclusion during an emergency situation if such restraint or seclusion is pursuant to or documented contemporaneously by the written order of a responsible mental health professional.

(G) The right to a humane treatment environment that affords reasonable protection from harm and appropriate privacy to such person with regard to personal needs.

(H) The right to confidentiality of such person's records.

(I) The right to access, upon request, to such person's mental health care records, except such person may be refused access to—

(i) information in such records provided by a third party under assurance that such information shall remain confidential; and

(ii) specific material in such records if the health professional responsible for the mental health services concerned has made a determination in writing that such access would be detrimental to such person's health, except that such material may be made available to a similarly licensed health professional selected by such person and such health professional may, in the exercise of professional judgment, provide such person with access to any or all parts of such material or otherwise disclose the information contained in such material to such person.

(J) The right, in the case of a person admitted on a residential or inpatient care basis, to converse with others privately, to have convenient and reasonable access to the telephone and mails, and to see visitors during regularly scheduled hours, except that, if a mental health profes-

sional treating such person determines that denial of access to a particular visitor is necessary for treatment purposes, such mental health professional may, for a specific, limited, and reasonable period of time, deny such access if such mental health professional has ordered such denial in writing and such order has been incorporated in the treatment plan for such person. An order denying such access should include the reasons for such denial.

(K) The right to be informed promptly at the time of admission and periodically thereafter, in language and terms appropriate to such person's condition and ability to understand, of the rights described in this section.

(L) The right to assert grievances with respect to infringement of the rights described in this section, including the right to have such grievances considered in a fair, timely, and impartial grievance procedure provided for or by the program or facility.

(M) Notwithstanding subparagraph (J), the right of access to (including the opportunities and facilities for private communication with) any available—

(i) rights protection service within the program or facility;

(ii) rights protection service within the State mental health system designed to be available to such person;

(iii) system established under title I to protect and advocate the rights of individuals with mental illness; and

(iv) qualified advocate;

for the purpose of receiving assistance to understand, exercise, and protect the rights described in this section and in other provisions of law.

(N) The right to exercise the rights described in this section without reprisal, including reprisal in the form of denial of any appropriate, available treatment.

(O) The right to referral as appropriate to other providers of mental health services upon discharge.

(2)(A) The rights described in this section should be in addition to and not in derogation of any other statutory or constitutional rights.

(B) The rights to confidentiality of and access to records as provided in subparagraphs (H) and (I) of paragraph (1) should remain applicable to records pertaining to a person after such person's discharge from a program or facility.

(3)(A) No otherwise eligible person should be denied admission to a program or facility for mental health services as a reprisal for the exercise of the rights described in this section.

(B) Nothing in this section should—

(i) obligate an individual mental health or health professional to administer treatment contrary to such professional's clinical judgment;

(ii) prevent any program or facility from discharging any person for whom the provision of appropriate treat-

ment, consistent with the clinical judgment of the mental health professional primarily responsible for such person's treatment, is or has become impossible as a result of such person's refusal to consent to such treatment;

(iii) require a program or facility to admit any person who, while admitted on prior occasions to such program or facility, has repeatedly frustrated the purposes of such admissions by withholding consent to proposed treatment; or

(iv) obligate a program or facility to provide treatment services to any person who is admitted to such program or facility solely for diagnostic or evaluative purposes.

(C) In order to assist a person admitted to a program or facility in the exercise or protection of such person's rights, such person's attorney or legal representatives should have reasonable access to—

(i) such person;

(ii) the areas of the program or facility where such person has received treatment, resided, or had access; and

(iii) pursuant to the written authorization of such person, the records and information pertaining to such person's diagnosis, treatment, and related services described in paragraph (1)(I).

(D) Each program and facility should post a notice listing and describing, in language and terms appropriate to the ability of the persons to whom such notice is addressed to understand, the rights described in this section of all persons admitted to such program or facility. Each such notice should conform to the format and content for such notices, and should be posted in all appropriate locations.

(4)(A) In the case of a person adjudicated by a court of competent jurisdiction as being incompetent to exercise the right to consent to treatment or experimentation described in subparagraph (D) or (E) of paragraph (1), or the right to confidentiality of or access to records described in subparagraph (H) or (I) of such paragraph, or to provide authorization as described in paragraph (3)(C)(iii), such right may be exercised or such authorization may be provided by the individual appointed by such court as such person's guardian or representative for the purpose of exercising such right or such authorization.

(B) In the case of a person who lacks capacity to exercise the right to consent to treatment or experimentation under subparagraph (D) or (E) of paragraph (1), or the right to confidentiality of or access to records described in subparagraph (H) or (I) of such paragraph, or to provide authorization as described in paragraph (3)(C)(iii), because such person has not attained an age considered sufficiently advanced under State law to permit the exercise of such right or such authorization to be legally binding, such right may be exercised or such authorization may be provided on behalf of such person by a parent or legal guardian of such person.

(C) Notwithstanding subparagraphs (A) and (B), in the case of a person admitted to a program or facility for the purpose of receiving mental health services, no individual em-

ployed by or receiving any remuneration from such program or facility should act as such person's guardian or representative.

TITLE III—CONSTRUCTION

CONSTRUCTION

SEC. 301. [10851] (a) Titles I and II shall not be construed as establishing any new rights for individuals with mental illness.

(b) For purposes of this section, the term "individual with mental illness" has the same meaning as in section 102(3).¹

TITLE IV—OTHER PROGRAMS²

* * * * *

BALANCED BUDGET PROVISION

SEC. 402. [10801 note] This Act shall not be construed as superseding any of the balanced budget provisions set forth in section 3(7) of the Congressional Budget and Impoundment Control Act of 1974.

¹So in original. Probably should be "section 102(4)". See the redesignations made by section 4(1) of Public Law 102-173 (105 Stat. 1217).

²The Act contains a section 401. The section amended part B of title III of the Public Health Service Act to add a new section 316 regarding family support groups for Alzheimer's disease patients.

HEALTH CARE QUALITY IMPROVEMENT ACT OF 1986

HEALTH CARE QUALITY IMPROVEMENT ACT OF 1986¹

(References in brackets [] are to title 42, United States Code)

SEC. 401. [11101 note] SHORT TITLE.

This title may be cited as the "Health Care Quality Improvement Act of 1986".

SEC. 402. [11101] FINDINGS.

The Congress finds the following:

(1) The increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems that warrant greater efforts than those that can be undertaken by any individual State.

(2) There is a national need to restrict the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance.

(3) This nationwide problem can be remedied through effective professional peer review.

(4) The threat of private money damage liability under Federal laws, including treble damage liability under Federal antitrust law, unreasonably discourages physicians from participating in effective professional peer review.

(5) There is an overriding national need to provide incentive and protection for physicians engaging in effective professional peer review.

PART A—PROMOTION OF PROFESSIONAL REVIEW ACTIVITIES

SEC. 411. [11111] PROFESSIONAL REVIEW.

(a) IN GENERAL.—

(1) LIMITATION ON DAMAGES FOR PROFESSIONAL REVIEW ACTIONS.—If a professional review action (as defined in section 431(9)) of a professional review body meets all the standards specified in section 412(a), except as provided in subsection (b)—

(A) the professional review body,

(B) any person acting as a member or staff to the body,

(C) any person under a contract or other formal agreement with the body, and

(D) any person who participates with or assists the body with respect to the action,

shall not be liable in damages under any law of the United States or of any State (or political subdivision thereof) with re-

¹ Title IV of Public Law 99-660.

spect to the action. The preceding sentence shall not apply to damages under any law of the United States or any State relating to the civil rights of any person or persons, including the Civil Rights Act of 1964, 42 U.S.C. 2000e, et seq. and the Civil Rights Acts, 42 U.S.C. 1981, et seq. Nothing in this paragraph shall prevent the United States or any Attorney General of a State from bringing an action, including an action under section 4C of the Clayton Act, 15 U.S.C. 15C, where such an action is otherwise authorized.

(2) PROTECTION FOR THOSE PROVIDING INFORMATION TO PROFESSIONAL REVIEW BODIES.—Notwithstanding any other provision of law, no person (whether as a witness or otherwise) providing information to a professional review body regarding the competence or professional conduct of a physician shall be held, by reason of having provided such information, to be liable in damages under any law of the United States or of any State (or political subdivision thereof) unless such information is false and the person providing it knew that such information was false.

(b) EXCEPTION.—If the Secretary has reason to believe that a health care entity has failed to report information in accordance with section 423(a), the Secretary shall conduct an investigation. If, after providing notice of noncompliance, an opportunity to correct the noncompliance, and an opportunity for a hearing, the Secretary determines that a health care entity has failed substantially to report information in accordance with section 423(a), the Secretary shall publish the name of the entity in the Federal Register. The protections of subsection (a)(1) shall not apply to an entity the name of which is published in the Federal Register under the previous sentence with respect to professional review actions of the entity commenced during the 3-year period beginning 30 days after the date of publication of the name.

(c) TREATMENT UNDER STATE LAWS.—

(1) PROFESSIONAL REVIEW ACTIONS TAKEN ON OR AFTER OCTOBER 14, 1989.—Except as provided in paragraph (2), subsection (a) shall apply to State laws in a State only for professional review actions commenced on or after October 14, 1989.

(2) EXCEPTIONS.—

(A) STATE EARLY OPT-IN.—Subsection (a) shall apply to State laws in a State for actions commenced before October 14, 1989, if the State by legislation elects such treatment.

(B) EFFECTIVE DATE OF ELECTION.—An election under State law is not effective, for purposes of, ¹ for actions commenced before the effective date of the State law, which may not be earlier than the date of the enactment of that law.

¹So in original. Probably should be "for purposes of subparagraph (A)". The provision formerly made a reference to "subparagraphs (A) and (B)". Section 6103(e)(6) of Public Law 101-239 struck out this reference, after having struck former subparagraph (B). (Former subparagraph (C) was redesignated as subparagraph (B).)

SEC. 412. [11112] STANDARDS FOR PROFESSIONAL REVIEW ACTIONS.

(a) **IN GENERAL.**—For purposes of the protection set forth in section 411(a), a professional review action must be taken—

(1) in the reasonable belief that the action was in the furtherance of quality health care,

(2) after a reasonable effort to obtain the facts of the matter,

(3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and

(4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3).

A professional review action shall be presumed to have met the preceding standards necessary for the protection set out in section 411(a) unless the presumption is rebutted by a preponderance of the evidence.

(b) **ADEQUATE NOTICE AND HEARING.**—A health care entity is deemed to have met the adequate notice and hearing requirement of subsection (a)(3) with respect to a physician if the following conditions are met (or are waived voluntarily by the physician):

(1) **NOTICE OF PROPOSED ACTION.**—The physician has been given notice stating—

(A)(i) that a professional review action has been proposed to be taken against the physician,

(ii) reasons for the proposed action,

(B)(i) that the physician has the right to request a hearing on the proposed action,

(ii) any time limit (of not less than 30 days) within which to request such a hearing, and

(C) a summary of the rights in the hearing under paragraph (3).

(2) **NOTICE OF HEARING.**—If a hearing is requested on a timely basis under paragraph (1)(B), the physician involved must be given notice stating—

(A) the place, time, and date, of the hearing, which date shall not be less than 30 days after the date of the notice, and

(B) a list of the witnesses (if any) expected to testify at the hearing on behalf of the professional review body.

(3) **CONDUCT OF HEARING AND NOTICE.**—If a hearing is requested on a timely basis under paragraph (1)(B)—

(A) subject to subparagraph (B), the hearing shall be held (as determined by the health care entity)—

(i) before an arbitrator mutually acceptable to the physician and the health care entity,

(ii) before a hearing officer who is appointed by the entity and who is not in direct economic competition with the physician involved, or

(iii) before a panel of individuals who are appointed by the entity and are not in direct economic competition with the physician involved;

(B) the right to the hearing may be forfeited if the physician fails, without good cause, to appear;

(C) in the hearing the physician involved has the right—

(i) to representation by an attorney or other person of the physician's choice,

(ii) to have a record made of the proceedings, copies of which may be obtained by the physician upon payment of any reasonable charges associated with the preparation thereof,

(iii) to call, examine, and cross-examine witnesses,

(iv) to present evidence determined to be relevant by the hearing officer, regardless of its admissibility in a court of law, and

(v) to submit a written statement at the close of the hearing; and

(D) upon completion of the hearing, the physician involved has the right—

(i) to receive the written recommendation of the arbitrator, officer, or panel, including a statement of the basis for the recommendations, and

(ii) to receive a written decision of the health care entity, including a statement of the basis for the decision.

A professional review body's failure to meet the conditions described in this subsection shall not, in itself, constitute failure to meet the standards of subsection (a)(3).

(c) ADEQUATE PROCEDURES IN INVESTIGATIONS OR HEALTH EMERGENCIES.—For purposes of section 411(a), nothing in this section shall be construed as—

(1) requiring the procedures referred to in subsection (a)(3)—

(A) where there is no adverse professional review action taken, or

(B) in the case of a suspension or restriction of clinical privileges, for a period of not longer than 14 days, during which an investigation is being conducted to determine the need for a professional review action; or

(2) precluding an immediate suspension or restriction of clinical privileges, subject to subsequent notice and hearing or other adequate procedures, where the failure to take such an action may result in an imminent danger to the health of any individual.

SEC. 413. [11113] PAYMENT OF REASONABLE ATTORNEYS' FEES AND COSTS IN DEFENSE OF SUIT.

In any suit brought against a defendant, to the extent that a defendant has met the standards set forth under section 412(a) and the defendant substantially prevails, the court shall, at the conclusion of the action, award to a substantially prevailing party defending against any such claim the cost of the suit attributable to such claim, including a reasonable attorney's fee, if the claim, or the claimant's conduct during the litigation of the claim, was frivolous, unreasonable, without foundation, or in bad faith. For the purposes of this section, a defendant shall not be considered to have substantially prevailed when the plaintiff obtains an award for damages or permanent injunctive or declaratory relief.

SEC. 414. [11114] GUIDELINES OF THE SECRETARY.

The Secretary may establish, after notice and opportunity for comment, such voluntary guidelines as may assist the professional review bodies in meeting the standards described in section 412(a).

SEC. 415. [11115] CONSTRUCTION.

(a) **IN GENERAL.**—Except as specifically provided in this part, nothing in this part shall be construed as changing the liabilities or immunities under law or as preempting or overriding any State law which provides incentives, immunities, or protection for those engaged in a professional review action that is in addition to or greater than that provided by this part.

(b) **SCOPE OF CLINICAL PRIVILEGES.**—Nothing in this part shall be construed as requiring health care entities to provide clinical privileges to any or all classes or types of physicians or other licensed health care practitioners.

(c) **TREATMENT OF NURSES AND OTHER PRACTITIONERS.**—Nothing in this part shall be construed as affecting, or modifying any provision of Federal or State law, with respect to activities of professional review bodies regarding nurses, other licensed health care practitioners, or other health professionals who are not physicians.

(d) **TREATMENT OF PATIENT MALPRACTICE CLAIMS.**—Nothing in this title shall be construed as affecting in any manner the rights and remedies afforded patients under any provision of Federal or State law to seek redress for any harm or injury suffered as a result of negligent treatment or care by any physician, health care practitioner, or health care entity, or as limiting any defenses or immunities available to any physician, health care practitioner, or health care entity.

SEC. 416. [11111 note] EFFECTIVE DATE.

This part shall apply to professional review actions commenced on or after the date of the enactment of this Act.

PART B—REPORTING OF INFORMATION**SEC. 421. [11131] REQUIRING REPORTS ON MEDICAL MALPRACTICE PAYMENTS.**

(a) **IN GENERAL.**—Each entity (including an insurance company) which makes payment under a policy of insurance, self-insurance, or otherwise in settlement (or partial settlement) of, or in satisfaction of a judgment in, a medical malpractice action or claim shall report, in accordance with section 424, information respecting the payment and circumstances thereof.

(b) **INFORMATION TO BE REPORTED.**—The information to be reported under subsection (a) includes—

(1) the name of any physician or licensed health care practitioner for whose benefit the payment is made,

(2) the amount of the payment,

(3) the name (if known) of any hospital with which the physician or practitioner is affiliated or associated,

(4) a description of the acts or omissions and injuries or illnesses upon which the action or claim was based, and

(5) such other information as the Secretary determines is required for appropriate interpretation of information reported under this section.

(c) **SANCTIONS FOR FAILURE TO REPORT.**—Any entity that fails to report information on a payment required to be reported under this section shall be subject to a civil money penalty of not more than \$10,000 for each such payment involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected under that section.

(d) **REPORT ON TREATMENT OF SMALL PAYMENTS.**—The Secretary shall study and report to Congress, not later than two years after the date of the enactment of this Act, on whether information respecting small payments should continue to be required to be reported under subsection (a) and whether information respecting all claims made concerning a medical malpractice action should be required to be reported under such subsection.

SEC. 422. [1132] REPORTING OF SANCTIONS TAKEN BY BOARDS OF MEDICAL EXAMINERS.

(a) **IN GENERAL.**—

(1) **ACTIONS SUBJECT TO REPORTING.**—Each Board of Medical Examiners—

(A) which revokes or suspends (or otherwise restricts) a physician's license or censures, reprimands, or places on probation a physician, for reasons relating to the physician's professional competence or professional conduct, or

(B) to which a physician's license is surrendered, shall report, in accordance with section 424, the information described in paragraph (2).

(2) **INFORMATION TO BE REPORTED.**—The information to be reported under paragraph (1) is—

(A) the name of the physician involved,

(B) a description of the acts or omissions or other reasons (if known) for the revocation, suspension, or surrender of license, and

(C) such other information respecting the circumstances of the action or surrender as the Secretary deems appropriate.

(b) **FAILURE TO REPORT.**—If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board of Medical Examiners has failed to report information in accordance with subsection (a), the Secretary shall designate another qualified entity for the reporting of information under section 423.

SEC. 423. [1133] REPORTING OF CERTAIN PROFESSIONAL REVIEW ACTIONS TAKEN BY HEALTH CARE ENTITIES.

(a) **REPORTING BY HEALTH CARE ENTITIES.**—

(1) **ON PHYSICIANS.**—Each health care entity which—

(A) takes a professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days;

(B) accepts the surrender of clinical privileges of a physician—

(i) while the physician is under an investigation by the entity relating to possible incompetence or improper professional conduct, or

(ii) in return for not conducting such an investigation or proceeding; or

(C) in the case of such an entity which is a professional society, takes a professional review action which adversely affects the membership of a physician in the society,

shall report to the Board of Medical Examiners, in accordance with section 424(a), the information described in paragraph (3).

(2) **PERMISSIVE REPORTING ON OTHER LICENSED HEALTH CARE PRACTITIONERS.**—A health care entity may report to the Board of Medical Examiners, in accordance with section 424(a), the information described in paragraph (3) in the case of a licensed health care practitioner who is not a physician, if the entity would be required to report such information under paragraph (1) with respect to the practitioner if the practitioner were a physician.

(3) **INFORMATION TO BE REPORTED.**—The information to be reported under this subsection is—

(A) the name of the physician or practitioner involved,

(B) a description of the acts or omissions or other reasons for the action or, if known, for the surrender, and

(C) such other information respecting the circumstances of the action or surrender as the Secretary deems appropriate.

(b) **REPORTING BY BOARD OF MEDICAL EXAMINERS.**—Each Board of Medical Examiners shall report, in accordance with section 424, the information reported to it under subsection (a) and known instances of a health care entity's failure to report information under subsection (a)(1).

(c) **SANCTIONS.**—

(1) **HEALTH CARE ENTITIES.**—A health care entity that fails substantially to meet the requirement of subsection (a)(1) shall lose the protections of section 411(a)(1) if the Secretary publishes the name of the entity under section 411(b).

(2) **BOARD OF MEDICAL EXAMINERS.**—If, after notice of non-compliance and providing an opportunity to correct noncompliance, the Secretary determines that a Board of Medical Examiners has failed to report information in accordance with subsection (b), the Secretary shall designate another qualified entity for the reporting of information under subsection (b).

(d) **REFERENCES TO BOARD OF MEDICAL EXAMINERS.**—Any reference in this part to a Board of Medical Examiners includes, in the case of a Board in a State that fails to meet the reporting requirements of section 422(a) or subsection (b), a reference to such other qualified entity as the Secretary designates.

SEC. 424. [11134] FORM OF REPORTING.

(a) **TIMING AND FORM.**—The information required to be reported under sections 421, 422(a), and 423 shall be reported regularly (but not less often than monthly) and in such form and manner as the Secretary prescribes. Such information shall first be required to be reported on a date (not later than one year after the date of the enactment of this Act) specified by the Secretary.

(b) **TO WHOM REPORTED.**—The information required to be reported under sections 421, 422(a), and 423(b) shall be reported to the Secretary, or, in the Secretary's discretion, to an appropriate private or public agency which has made suitable arrangements with the Secretary with respect to receipt, storage, protection of confidentiality, and dissemination of the information under this part.

(c) **REPORTING TO STATE LICENSING BOARDS.**—

(1) **MALPRACTICE PAYMENTS.**—Information required to be reported under section 421 shall also be reported to the appropriate State licensing board (or boards) in the State in which the medical malpractice claim arose.

(2) **REPORTING TO OTHER LICENSING BOARDS.**—Information required to be reported under section 423(b) shall also be reported to the appropriate State licensing board in the State in which the health care entity is located if it is not otherwise reported to such board under subsection (b).

SEC. 425. [11135] DUTY OF HOSPITALS TO OBTAIN INFORMATION.

(a) **IN GENERAL.**—It is the duty of each hospital to request from the Secretary (or the agency designated under section 424(b)), on and after the date information is first required to be reported under section 424(a)—

(1) at the time a physician or licensed health care practitioner applies to be on the medical staff (courtesy or otherwise) of, or for clinical privileges at, the hospital, information reported under this part concerning the physician or practitioner, and

(2) once every 2 years information reported under this part concerning any physician or such practitioner who is on the medical staff (courtesy or otherwise) of, or has been granted clinical privileges at, the hospital.

A hospital may request such information at other times.

(b) **FAILURE TO OBTAIN INFORMATION.**—With respect to a medical malpractice action, a hospital which does not request information respecting a physician or practitioner as required under subsection (a) is presumed to have knowledge of any information reported under this part to the Secretary with respect to the physician or practitioner.

(c) **RELIANCE ON INFORMATION PROVIDED.**—Each hospital may rely upon information provided to the hospital under this title and shall not be held liable for such reliance in the absence of the hospital's knowledge that the information provided was false.

SEC. 426. [11136] DISCLOSURE AND CORRECTION OF INFORMATION.

With respect to the information reported to the Secretary (or the agency designated under section 424(b)) under this part respecting a physician or other licensed health care practitioner, the Secretary shall, by regulation, provide for—

(1) disclosure of the information, upon request, to the physician or practitioner, and

(2) procedures in the case of disputed accuracy of the information.

SEC. 427. [11137] MISCELLANEOUS PROVISIONS.

(a) **PROVIDING LICENSING BOARDS AND OTHER HEALTH CARE ENTITIES WITH ACCESS TO INFORMATION.**—The Secretary (or the agency designated under section 424(b)) shall, upon request, provide information reported under this part with respect to a physician or other licensed health care practitioner to State licensing boards, to hospitals, and to other health care entities (including health maintenance organizations) that have entered (or may be entering) into an employment or affiliation relationship with the physician or practitioner or to which the physician or practitioner has applied for clinical privileges or appointment to the medical staff.

(b) **CONFIDENTIALITY OF INFORMATION.**—

(1) **IN GENERAL.**—Information reported under this part is considered confidential and shall not be disclosed (other than to the physician or practitioner involved) except with respect to professional review activity, as necessary to carry out subsections (b) and (c) of section 425 (as specified in regulations by the Secretary), or in accordance with regulations of the Secretary promulgated pursuant to subsection (a). Nothing in this subsection shall prevent the disclosure of such information by a party which is otherwise authorized, under applicable State law, to make such disclosure. Information reported under this part that is in a form that does not permit the identification of any particular health care entity, physician, other health care practitioner, or patient shall not be considered confidential. The Secretary (or the agency designated under section 424(b)), on application by any person, shall prepare such information in such form and shall disclose such information in such form.

(2) **PENALTY FOR VIOLATIONS.**—Any person who violates paragraph (1) shall be subject to a civil money penalty of not more than \$10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected under that section.

(3) **USE OF INFORMATION.**—Subject to paragraph (1), information provided under section 425 and subsection (a) is intended to be used solely with respect to activities in the furtherance of the quality of health care.

(4) **FEES.**—The Secretary may establish or approve reasonable fees for the disclosure of information under this section or section 426. The amount of such a fee may not exceed the costs of processing the requests for disclosure and of providing such information. Such fees shall be available to the Secretary (or, in the Secretary's discretion, to the agency designated under section 424(b)) to cover such costs.

(c) **RELIEF FROM LIABILITY FOR REPORTING.**—No person or entity (including the agency designated under section 424(b)) shall be held liable in any civil action with respect to any report made under this part (including information provided under subsection

(a)¹ without knowledge of the falsity of the information contained in the report.

(d) **INTERPRETATION OF INFORMATION.**—In interpreting information reported under this part, a payment in settlement of a medical malpractice action or claim shall not be construed as creating a presumption that medical malpractice has occurred.

PART C—DEFINITIONS AND REPORTS

SEC. 431. [11151] DEFINITIONS.

In this title:

(1) The term “adversely affecting” includes reducing, restricting, suspending, revoking, denying, or failing to renew clinical privileges or membership in a health care entity.

(2) The term “Board of Medical Examiners” includes a body comparable to such a Board (as determined by the State) with responsibility for the licensing of physicians and also includes a subdivision of such a Board or body.

(3) The term “clinical privileges” includes privileges, membership on the medical staff, and the other circumstances pertaining to the furnishing of medical care under which a physician or other licensed health care practitioner is permitted to furnish such care by a health care entity.

(4)(A) The term “health care entity” means—

(i) a hospital that is licensed to provide health care services by the State in which it is located,

(ii) an entity (including a health maintenance organization or group medical practice) that provides health care services and that follows a formal peer review process for the purpose of furthering quality health care (as determined under regulations of the Secretary), and

(iii) subject to subparagraph (B), a professional society (or committee thereof) of physicians or other licensed health care practitioners that follows a formal peer review process for the purpose of furthering quality health care (as determined under regulations of the Secretary).

(B) The term “health care entity” does not include a professional society (or committee thereof) if, within the previous 5 years, the society has been found by the Federal Trade Commission or any court to have engaged in any anti-competitive practice which had the effect of restricting the practice of licensed health care practitioners.

(5) The term “hospital” means an entity described in paragraphs (1) and (7) of section 1861(e) of the Social Security Act.

(6) The terms “licensed health care practitioner” and “practitioner” mean, with respect to a State, an individual (other than a physician) who is licensed or otherwise authorized by the State to provide health care services.

(7) The term “medical malpractice action or claim” means a written claim or demand for payment based on a health care provider’s furnishing (or failure to furnish) health care services, and includes the filing of a cause of action, based on the

¹So in original. A closing parenthesis probably should follow “subsection (a)”.

law of tort, brought in any court of any State or the United States seeking monetary damages.

(8) The term "physician" means a doctor of medicine or osteopathy or a doctor of dental surgery or medical dentistry legally authorized to practice medicine and surgery or dentistry by a State (or any individual who, without authority holds himself or herself out to be so authorized).

(9) The term "professional review action" means an action or recommendation of a professional review body which is taken or made in the conduct of professional review activity, which is based on the competence or professional conduct of an individual physician (which conduct affects or could affect adversely the health or welfare of a patient or patients), and which affects (or may affect) adversely the clinical privileges, or membership in a professional society, of the physician. Such term includes a formal decision of a professional review body not to take an action or make a recommendation described in the previous sentence and also includes professional review activities relating to a professional review action. In this title, an action is not considered to be based on the competence or professional conduct of a physician if the action is primarily based on—

(A) the physician's association, or lack of association, with a professional society or association,

(B) the physician's fees or the physician's advertising or engaging in other competitive acts intended to solicit or retain business,

(C) the physician's participation in prepaid group health plans, salaried employment, or any other manner of delivering health services whether on a fee-for-service or other basis,

(D) a physician's association with, supervision of, delegation of authority to, support for, training of, or participation in a private group practice with, a member or members of a particular class of health care practitioner or professional, or

(E) any other matter that does not relate to the competence or professional conduct of a physician.

(10) The term "professional review activity" means an activity of a health care entity with respect to an individual physician—

(A) to determine whether the physician may have clinical privileges with respect to, or membership in, the entity,

(B) to determine the scope or conditions of such privileges or membership, or

(C) to change or modify such privileges or membership.

(11) The term "professional review body" means a health care entity and the governing body or any committee of a health care entity which conducts professional review activity, and includes any committee of the medical staff of such an entity when assisting the governing body in a professional review activity.

(12) The term "Secretary" means the Secretary of Health and Human Services.

(13) The term "State" means the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(14) The term "State licensing board" means, with respect to a physician or health care provider in a State, the agency of the State which is primarily responsible for the licensing of the physician or provider to furnish health care services.

SEC. 432. [11152] REPORTS AND MEMORANDA OF UNDERSTANDING.

(a) **ANNUAL REPORTS TO CONGRESS.**—The Secretary shall report to Congress, annually during the three years after the date of the enactment of this Act, on the implementation of this title.

(b) **MEMORANDA OF UNDERSTANDING.**—The Secretary of Health and Human Services shall seek to enter into memoranda of understanding with the Secretary of Defense and the Administrator of Veterans' Affairs to apply the provisions of part B of this title to hospitals and other facilities and health care providers under the jurisdiction of the Secretary or Administrator, respectively. The Secretary shall report to Congress, not later than two years after the date of the enactment of this Act, on any such memoranda and on the cooperation among such officials in establishing such memoranda.

(c) **MEMORANDUM OF UNDERSTANDING WITH DRUG ENFORCEMENT ADMINISTRATION.**—The Secretary of Health and Human Services shall seek to enter into a memorandum of understanding with the Administrator of Drug Enforcement relating to providing for the reporting by the Administrator to the Secretary of information respecting physicians and other practitioners whose registration to dispense controlled substances has been suspended or revoked under section 304 of the Controlled Substances Act. The Secretary shall report to Congress, not later than two years after the date of the enactment of this Act, on any such memorandum and on the cooperation between the Secretary and the Administrator in establishing such a memorandum.

**ALZHEIMER'S DISEASE AND RELATED DEMENTIAS
RESEARCH ACT OF 1992**

ALZHEIMER'S DISEASE AND RELATED DEMENTIAS RESEARCH ACT OF 1992

(References in brackets [] are to title 42, United States Code)

TITLE IX—ALZHEIMER'S DISEASE AND RELATED DEMENTIAS RESEARCH¹

PART A—GENERAL PROVISIONS

SHORT TITLE

SEC. 901. [11201 note] This title may be cited as the "Alzheimer's Disease and Related Dementias Research Act of 1992".

FINDINGS

SEC. 902. [11201] The Congress finds that—

(1) best estimates indicate that between 2,000,000 and 3,000,000 Americans presently have Alzheimer's disease or related dementias;

(2) estimates of the number of individuals afflicted with Alzheimer's disease and related dementias are unreliable because current diagnostic procedures lack accuracy and sensitivity and because there is a need for epidemiological data on incidence and prevalence of such disease and dementias;

(3) studies estimate that between one-half and two-thirds of patients in nursing homes meet the clinical and mental status criteria for dementia;

(4) the cost of caring for individuals with Alzheimer's disease and related dementias is great, and conservative estimates range between \$38,000,000,000 and \$42,000,000,000 per year solely for direct costs;

(5) progress in the neurosciences and behavioral sciences has demonstrated the interdependence and mutual reinforcement of basic science, clinical research, and services research for Alzheimer's disease and related dementias;

(6) programs initiated as part of the Decade of the Brain are likely to provide significant progress in understanding the fundamental mechanisms underlying the causes of, and treatments for, Alzheimer's disease and related dementias;

(7) although substantial progress has been made in recent years in identifying possible leads to the causes of Alzheimer's disease and related dementias, and more progress can be expected in the near future, there is little likelihood of a breakthrough in the immediate future that would eliminate or substantially reduce—

¹ Title IX of Public Law 99-660.

(A) the number of individuals with the disease and dementias; or

(B) the difficulties of caring for the individuals;

(8) the responsibility for care of individuals with Alzheimer's disease and related dementias falls primarily on their families, and the care is financially and emotionally devastating;

(9) attempts to reduce the emotional and financial burden of caring for dementia patients is impeded by a lack of knowledge about such patients, how to care for such patients, the costs associated with such care, the effectiveness of various modes of care, the quality and type of care necessary at various stages of the disease, and other appropriate services that are needed to provide quality care;

(10) the results of the little research that has been undertaken concerning dementia has been inadequate or the results have not been widely disseminated;

(11) more knowledge is needed concerning—

(A) the epidemiology of, and the identification of risk factors for, Alzheimer's disease and related dementias;

(B) the development of methods for early diagnosis, functional assessment, and psychological evaluation of individuals with Alzheimer's disease for the purpose of monitoring the course of the disease and developing strategies for improving the quality of life for such individuals;

(C) the understanding of the optimal range and cost-effectiveness of community and institutional services for individuals with Alzheimer's disease and related dementias and their families, particularly with respect to the design, delivery, staffing, and mix of such services and the coordination of such services with other services, and with respect to the relationship of formal to informal support services;

(D) the understanding of optimal methods to combine formal support services provided by health care professionals with informal support services provided by family, friends, and neighbors of individuals with Alzheimer's disease, and the identification of ways family caregivers can be sustained through interventions to reduce psychological and social problems and physical problems induced by stress;

(E) existing data that are relevant to Alzheimer's disease and related dementias; and

(F) the costs incurred in caring for individuals with Alzheimer's disease and related dementias;

(12) it is imperative to provide appropriate coordination of the efforts of the Federal Government in the provision of services for individuals with Alzheimer's disease and related dementias;

(13) it is important to increase the understanding of Alzheimer's disease and related dementias by the diverse range of personnel involved in the care of individuals with such disease and dementias; and

(14) it is imperative that the Social Security Administration be provided information pertaining to Alzheimer's disease and related dementias, particularly for personnel in such Administration involved in the establishment and updating of criteria for determining whether an individual is under a disability for purposes of titles II and XVI of the Social Security Act.

PART B—COUNCIL ON ALZHEIMER'S DISEASE

ESTABLISHMENT

SEC. 911. [11211] (a) There is established in the Department of Health and Human Services (hereinafter referred to as the "Department") the Council on Alzheimer's Disease (hereinafter referred to as the "Council"). The Council shall be composed of—

- (1) the Assistant Secretary for Health;
- (2) the Surgeon General of the Public Health Service;
- (3) the Assistant Secretary for Planning and Evaluation;
- (4) the Director of the National Institute of Allergy and Infectious Diseases;
- (5) the Director of the National Institute of Mental Health;
- (6) the Director of the National Institute of Neurological Disorders and Stroke;
- (7) the Director of the National Institute on Aging;
- (8) the Commissioner on Aging;¹
- (9) the Administrator of the Health Care Financing Administration (or the designee of such Administrator);
- (10) the Administrator of the Agency for Health Care Policy and Research;
- (11) the Administrator of the Health Resources and Services Administration;
- (12) the Director of the National Center for Nursing Research;²
- (13) the Chief Medical Director of the Department of Veterans Affairs;
- (14) the Director of the National Center for Health Statistics; and
- (15) such additional members as the Secretary of Health and Human Services (hereinafter referred to as the "Secretary") considers appropriate.

(b) The Assistant Secretary for Health shall serve as the Chairman of the Council.

(c) A majority of the members of the Council shall constitute a quorum, but a lesser number may hold hearings.

(d) The Council shall meet periodically at the call of the Chairman, but not less than once each year.

(e) The Secretary shall appoint an Executive Secretary for the Council and shall provide the Council with such additional admin-

¹Probably should be "Assistant Secretary for Aging". See section 3(b)(3) of Public Law 103-171 (107 Stat. 1991), which provides for an amendment to each of sections 911(a)(8) and 921(a)(2) of the "Alzheimer's Disease and Related Dementias Act of 1986". The amendments cannot be executed because there no longer is any Act with that short title. See section 2(a) of Public Law 102-507 (106 Stat. 3281), which changed the short title of this Act to the "Alzheimer's Disease and Related Dementias Research Act of 1992".

²Now the National Institute of Nursing Research.

istrative staff and support as may be necessary to enable the Council to carry out its functions.

FUNCTIONS

SEC. 912. [11212] (a) The Council shall—

(1) coordinate continuing research conducted by or through the Department on Alzheimer's disease and related dementias;

(2) establish a mechanism for the sharing of information among all officers and employees of the Department involved in carrying out programs serving elderly individuals;

(3) identify the most promising areas of research concerning Alzheimer's disease and related dementias; and

(4) establish mechanisms to use the results of research concerning Alzheimer's disease and related dementias in the development of policies, programs, and means to improve the quality of life for older Americans.

(b)(1) The Chairman of the Council shall submit to the committees listed in paragraph (2) an annual report containing information on—

(A) progress made by research, sponsored by the Federal Government, on Alzheimer's disease and related dementias; and

(B) new directions that the Council considers potentially important in research on Alzheimer's disease and related dementias.

(2) The Chairman of the Council shall submit the report described in paragraph (1) to—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Ways and Means of the House of Representatives;

(C) the Committee on Veterans' Affairs of the House of Representatives;

(D) the Committee on Appropriations of the House of Representatives;

(E) the Committee on Labor and Human Resources of the Senate;

(F) the Committee on Finance of the Senate;

(G) the Committee on Veterans' Affairs of the Senate; and

(H) the Committee on Appropriations of the Senate.

PART C—ADVISORY PANEL ON ALZHEIMER'S DISEASE

ESTABLISHMENT OF PANEL

SEC. 921. [11221] (a) There is established in the Department the Advisory Panel on Alzheimer's Disease (hereinafter referred to as the "Panel"). The Panel shall be composed of—

(1) 15 voting members appointed by the Director of the Office of Technology Assessment, of which—

(A) 3 shall be individuals who are biomedical research scientists with demonstrated achievements in biomedical research relating to Alzheimer's disease, including at least one individual who is a researcher at a center supported under section 445 of the Public Health Service Act;

(B) 3 shall be individuals with demonstrated achievements in research relevant to services for the care of individuals with Alzheimer's disease and related dementias;

(C) 3 shall be individuals who are providers of services, or administrators of organizations which provide services, for individuals with Alzheimer's disease and related dementias and their families;

(D) 3 shall be individuals who are experts in the financing of health care services and long-term care services, including one individual who is a representative of private health care services insurers; and

(E) 3 shall be representatives of national voluntary organizations which are concerned with the problems of individuals with Alzheimer's disease and related dementias and their families; and

(2) the Chairman of the Council, the Director of the National Institute on Aging, the Director of the National Institute of Mental Health, the Administrator of the Agency for Health Care Policy and Research, and the Commissioner on Aging¹, who shall be nonvoting ex officio members.

(b) The Director of the Office of Technology Assessment shall appoint members to the Panel under subsection (a)(1) within 90 days after the date of enactment of this Act.

(c) The Secretary shall appoint a Chairman of the Panel from among the members appointed under subsection (a)(1).

(d)(1)(A) Except as provided in subparagraph (B), members of the Panel appointed under subsection (a)(1) shall each serve for a term of 3 years.

(B) Of the members appointed under subsection (a)(1) that are serving on the Panel on the day before the date of the enactment of this subsection—

(i) five shall serve for a term that expires on such date;

(ii) five shall serve for a term that expires 1 year after such date; and

(iii) five shall serve for a term that expires 2 years after such date.

(2) A vacancy on the Panel shall be filled in the same manner as the original appointment was made, and not later than 90 days after the date on which the vacancy first arises. A vacancy on the Panel shall not affect the powers of the Panel.

(e) A majority of the members of the Panel appointed under subsection (a)(1) shall constitute a quorum, but a lesser number may hold hearings. The Panel may establish such subcommittees as the Panel considers appropriate.

(f) The Panel shall meet at the call of the Chairman, but not less than once per year.

(g) The Executive Secretary of the Council shall serve as Executive Secretary of the Panel. The Secretary shall provide the Panel with such additional administrative staff and support as may be necessary to enable the Panel to carry out its functions.

(h) Each member of the Panel appointed under subsection (a)(1) shall receive compensation at a rate at the daily equivalent

¹Probably should be "Assistant Secretary for Aging". See footnote 1 on page 1015.

of the maximum rate specified for GS-15 of the General Schedule under section 5332 of title 5, United States Code, for each day, including travel time, that such member is engaged in duties as a member of the Panel. While away from their homes or regular places of business in the performance of duties as a member of the Panel, members of the Panel appointed under subsection (a)(1) shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under section 5702 of title 5, United States Code.

(i) Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), on September 30, 1996, the Panel shall be abolished and all programs established under this part shall terminate.

FUNCTIONS OF THE PANEL

SEC. 922. [11222] (a) The Panel shall assist the Secretary and the Council in the identification of priorities and emerging issues with respect to Alzheimer's disease and related dementias and the care of individuals with such disease and dementias. The Panel shall advise the Secretary and the Council with respect to the identification of—

(1) emerging issues in, and promising areas of, biomedical research relating to Alzheimer's disease and related dementias;

(2) emerging issues in, and promising areas of, research relating to services for individuals with Alzheimer's disease and related dementias and their families;

(3) emerging issues and promising initiatives in home and community based services, and systems of such services, for individuals with Alzheimer's disease and related dementias and their families; and

(4) emerging issues in, and innovative financing mechanisms for, payment for health care services and social services for individuals with Alzheimer's disease and related dementias and their families, particularly financing mechanisms in the private sector.

(b) The Panel shall prepare and transmit to the Congress, the Secretary, and the Council, and make available to the public, an annual report. Such report shall contain such recommendations as the Panel considers appropriate for administrative and legislative actions to improve services for individuals with Alzheimer's disease and related dementias and their families and to provide for promising biomedical research relating to Alzheimer's disease and related dementias.

SEC. 923. [11223] AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this part such sums as may be necessary for each of the fiscal years 1992 through 1996.

PART D—RESEARCH RELATING TO SERVICES FOR INDIVIDUALS WITH ALZHEIMER'S DISEASE AND RELATED DEMENTIAS AND THEIR FAMILIES

Subpart 1—Responsibilities of the National Institute of Mental Health

RESEARCH PROGRAM AND PLAN

SEC. 931. [11251] (a) The Director of the National Institute of Mental Health shall conduct, or make grants for the conduct of, research relevant to appropriate services and specialized care for individuals with Alzheimer's disease and related dementias and their families.

(b) The Director of the National Institute of Mental Health shall—

- (1) ensure that the research conducted under subsection (a) includes research concerning—

(A) mental health services and treatment modalities relevant to the mental, behavioral, and psychological problems associated with Alzheimer's disease and related dementias;

(B) the most effective methods for providing comprehensive multidimensional assessments to obtain information about the current functioning of, and needs for the care of, individuals with Alzheimer's disease and related dementias;

(C)¹ the optimal range, types, and cost-effectiveness of services and specialized care for individuals with Alzheimer's disease and related dementias and for their families, in community and residential settings (including home care, day care, and respite care), and in institutional settings, particularly with respect to—

- (i) the design of the services and care;
- (ii) appropriate staffing for the provision of the services and care;
- (iii) the timing of the services and care during the progression of the disease or dementias; and
- (iv) the appropriate mix and coordination of the services and specialized care;

(D) the efficacy of various special care units in the United States for individuals with Alzheimer's disease, including an assessment of the costs incurred in operating such units, the evaluation of best practices for the development of appropriate standards to be used by such units, and the measurement of patient outcomes in such units;

(E) methods to combine formal support services provided by health care professionals for individuals with Alzheimer's disease and related dementias with informal support services provided for such individuals by their families, friends, and neighbors, including services such as day

¹ Indentation is so in law. See paragraphs (1) and (2) of section 7(a) of Public Law 102-507 (106 Stat. 3284).

care services, respite care services, home care services, nursing home services, and other residential services and care, and an evaluation of the services actually used for such individuals and the sources of payment for such services;

(F) methods to sustain family members who provide care for individuals with Alzheimer's disease and related dementias through interventions to reduce psychological and social problems and physical problems induced by stress; and

(G) improved methods to deliver services for individuals with Alzheimer's disease and related dementias and their families, including services such as outreach services, comprehensive assessment and care management services, outpatient treatment services, home care services, respite care services, adult day care services, partial hospitalization services, nursing home services, and other residential services and care; and

(2) ensure that the research is coordinated with, and uses, to the maximum extent feasible, resources of, other Federal programs relating to Alzheimer's disease and dementia, including centers supported under section 445 of the Public Health Service Act, centers supported by the National Institute of Mental Health on the psychopathology of the elderly, relevant activities of the Administration on Aging, other programs and centers involved in research on Alzheimer's disease and related dementias supported by the Department, and other programs relating to Alzheimer's disease and related dementias which are planned or conducted by Federal agencies other than the Department, State or local agencies, community organizations, or private foundations.

DISSEMINATION

SEC. 932. [11252] The Director of the National Institute of Mental Health shall disseminate the results of research conducted under this subpart to appropriate professional entities and to the public.

SEC. 933. [11253] AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this subpart such sums as may be necessary for each of the fiscal years 1992 through 1996.

Subpart 2—Responsibilities of the Agency for Health Care Policy and Research

SEC. 934. [11261] RESEARCH PROGRAM.

(a) GRANTS FOR RESEARCH.—The Administrator of the Agency for Health Care Policy and Research shall conduct, or make grants for the conduct of, research relevant to appropriate services for individuals with Alzheimer's disease and related dementias and for their families.

(b) RESEARCH SUBJECTS.—The Administrator of the Agency for Health Care Policy and Research shall ensure that research conducted under subsection (a) shall include research—

(1) concerning improving the organization, delivery, and financing of services for individuals with Alzheimer's disease and related dementias and for their families, including research on—

(A) the design, staffing, and operation of special care units for the individuals in institutional settings, as well as individuals in institutional settings, as well as individuals in home care, day care, and respite care; and

(B) the exploration and enhancement of services such as home care, day care, and respite care, that provide alternatives to institutional care;

(2) concerning the costs incurred by individuals with Alzheimer's disease and related dementias and by their families in obtaining services, particularly services that are essential to the individuals and that are not generally required by other patients under long-term care programs;

(3) concerning the costs, cost-effectiveness, and effectiveness of various interventions to provide services for individuals with Alzheimer's disease and related dementias and for their families;

(4) conducted in consultation with the Director of the National Institute on Aging and the Commissioner of the Administration on Aging, concerning the role of physicians in caring for persons with Alzheimer's disease and related dementias and for their families, including the role of a physician in connecting such persons with appropriate health care and supportive services, including those supported through State and area agencies on aging designated under section 305(a) (1) and (2)(A) of the Older Americans Act of 1965 (42 U.S.C. 3025(a)(1) and (2)(A)); and

(5) conducted in consultation with the Director of the National Institute on Aging and the Commissioner of the Administration on Aging, concerning legal and ethical issues, including issues associated with special care units, facing individuals with Alzheimer's disease and related dementias and facing their families.

DISSEMINATION

SEC. 935. [11262] The Director of the National Center for Health Services Research and Health Care Technology Assessment¹ shall disseminate the results of research conducted under this subpart to appropriate professional entities and to the public.

SEC. 936. [11263] AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this subpart such sums as may be necessary for each of the fiscal years 1992 through 1996.

¹ Superseded by the Agency for Health Care Policy and Research.

Subpart 3—Responsibilities of the Health Care Financing Administration

RESEARCH PROGRAM AND PLAN

SEC. 937. [11271] (a) The Administrator of the National Health Care Financing Administration shall conduct, or make grants for the conduct of, research relevant to appropriate services for individuals with Alzheimer's disease and related dementias and their families.

(b)(1) Within 6 months after the date of enactment of this Act, the Administrator of the Health Care Financing Administration shall prepare and transmit to the Chairman of the Council a plan for research to be conducted under (a)¹. The plan shall—

(A) provide for a determination of the types of services required by individuals with Alzheimer's disease and related dementias and their families to allow such individuals to remain living at home or in a community-based setting;

(B) provide for a determination of the costs of providing needed services to individuals with Alzheimer's disease and related dementias and their families, including the expenditures for institutional, home, and community-based services and the source of payment for such expenditures;

(C) provide for an assessment of the adequacy of benefits provided through the Medicare and Medicaid² programs and through private health insurance for needed services for individuals with Alzheimer's disease and related dementias and their families; and

(D) provide for a determination of the costs to the Medicare and Medicaid programs and to private health insurers (if available) of providing covered benefits to individuals with Alzheimer's disease and related dementias and their families.

(2) Within one year after transmitting the plan required under paragraph (1), and annually thereafter, the Administrator of the Health Care Financing Administration shall prepare and transmit to the Chairman of the Council such revisions of such plan as the Administrator considers appropriate.

(c) In preparing and revising the plan required by subsection (b), the Administrator of the Health Care Financing Administration shall consult with the Chairman of the Council and the heads of agencies within the Department.

DISSEMINATION

SEC. 938. [11272] The Administrator of the Health Care Financing Administration shall disseminate the results of research conducted under this subpart to appropriate professional entities and to the public.

AUTHORIZATIONS OF APPROPRIATIONS

SEC. 939. [11273] To carry out this subpart, there are authorized to be appropriated \$2,000,000 for each of fiscal years 1988 through 1991.

¹ So in original. Probably should be "subsection (a)".

² Titles XVIII and XIX of the Social Security Act.

PART E—EDUCATIONAL ACTIVITIES

PROVIDING INFORMATION FOR PERSONNEL OF THE SOCIAL SECURITY ADMINISTRATION

SEC. 961. [11291] (a) The Secretary shall develop a mechanism to ensure the prompt provision of the most current information concerning Alzheimer's disease and related dementias to the Commissioner of Social Security, particularly information which will increase the understanding of personnel of the Social Security Administration concerning such disease and dementias.

(b) The Commissioner of Social Security shall ensure that information received under subsection (a) is provided to personnel of the Social Security Administration, particularly personnel involved in the process of determining, for purposes of titles II and XVI of the Social Security Act, whether an individual is under a disability.

SEC. 962. [11292] EDUCATION OF THE PUBLIC, INDIVIDUALS WITH ALZHEIMER'S DISEASE AND THEIR FAMILIES, AND HEALTH AND LONG-TERM CARE PROVIDERS.

(a) TRAINING MODELS GRANTS.—

(1) GRANTS.—The Director of the National Institute on Aging may award grants to eligible entities to assist the entities in developing and evaluating model training programs—

(A) for—

(i) health care professionals, including mental health professionals;

(ii) health care paraprofessionals;

(iii) personnel, including information and referral, case management, and in-home services personnel (including personnel receiving support under the Older Americans Act of 1965 (42 U.S.C. 3001 et seq.)), providing supportive services to the elderly and the families of the elderly;

(iv) family caregivers providing care and treatment for individuals with Alzheimer's disease and related disorders; and

(v) personnel of local organizations (including community groups, business and labor groups, and religious, educational, and charitable organizations) that have traditionally not been involved in planning and developing long-term care services; and

(B) with attention to such variables as—

(i) curricula development for training and continuing education programs;

(ii) care setting; and

(iii) intervention technique.

(2) ELIGIBLE ENTITY.—To be eligible to receive grants under this subsection, an entity shall be—

(A) an educational institution providing training and education in medicine, psychology, nursing, social work, gerontology, or health care administration;

(B) an educational institution providing preparatory training and education of personnel for nursing homes, hospitals, and home or community settings; or

(C) an Alzheimer's Disease Research Center described in section 445(a) of the Public Health Service Act.

(b) EDUCATIONAL GRANTS.—The Director of the National Institute on Aging is authorized to make grants to public and nonprofit private entities to assist such entities in establishing programs, for educating health care providers and the families of individuals with Alzheimer's disease or related disorders, regarding—

(1) caring for individuals with such diseases or disorders; and

(2) the availability in the community of public and private sources of assistance, including financial assistance, for caring for such individuals.

(c) AWARD OF GRANTS.—In awarding grants under this section, the Director of the National Institute on Aging shall—

(1) award the grants on the basis of merit;

(2) award the grants in a manner that will ensure access to the programs described in subsections (a) and (b) by rural, minority, and underserved populations throughout the country; and

(3) ensure that the grants are distributed among the principal geographic regions of the United States.

(d) APPLICATION.—To be eligible to receive a grant under this section, an entity shall submit an application to the Director of the National Institute on Aging at such time, in such manner, and containing or accompanied by such information, as the Director may reasonably require, including, at a minimum, an assurance that the entity will coordinate programs provided under this section with the State agency designated under section 305(a)(1) of the Older Americans Act of 1965, in the State in which the entity will provide such programs.

(e) COORDINATION.—The Director of the National Institute on Aging shall coordinate the award of grants under this section with the heads of other appropriate agencies, including the Commissioner of the Administration on Aging.

EDUCATION PROGRAMS FOR SAFETY AND TRANSPORTATION PERSONNEL

SEC. 963. [11293] The Director of the National Institute on Aging, through centers supported under section 445 of the Public Health Service Act, training academies, and continuing education programs, shall conduct education and information dissemination activities concerning Alzheimer's disease and related dementias for personnel involved in ensuring the public safety and providing public transportation. Such activities shall be designed to enhance the ability of such personnel to respond appropriately to individuals with Alzheimer's disease and related dementias whom such personnel may encounter in the course of their employment.

AUTHORIZATION OF APPROPRIATIONS

SEC. 964. [11294] (a) To carry out sections 961 and 963, there are authorized to be appropriated \$1,000,000 for each of the fiscal years 1988 through 1991.

(b) There are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1992 through 1996, to carry out section 962.



**ABANDONED INFANTS ASSISTANCE
ACT OF 1988**

ABANDONED INFANTS ASSISTANCE ACT OF 1988¹

SECTION 1. SHORT TITLE.

This Act may be cited as the "Abandoned Infants Assistance Act of 1988".

SEC. 2. FINDINGS.

The Congress finds that—

(1) throughout the Nation, the number of infants and young children who have been exposed to drugs taken by their mothers during pregnancy has increased dramatically;

(2) the inability of parents who abuse drugs to provide adequate care for such infants and young children and a lack of suitable shelter homes for such infants and young children have led to the abandonment of such infants and young children in hospitals for extended periods;

(3) an unacceptable number of these infants and young children will be medically cleared for discharge, yet remain in hospitals as boarder babies;

(4) hospital-based child care for these infants and young children is extremely costly and deprives them of an adequate nurturing environment;

(5) training is inadequate for foster care personnel working with medically fragile infants and young children and infants and young children exposed to drugs;

(6) a particularly devastating development is the increase in the number of infants and young children who are infected with the human immunodeficiency virus (which is believed to cause acquired immune deficiency syndrome and which is commonly known as HIV) or who have been perinatally exposed to the virus or to a dangerous drug;

(7) many such infants and young children have at least one parent who is an intravenous drug abuser;

(8) such infants and young children are particularly difficult to place in foster homes, and are being abandoned in hospitals in increasing numbers by mothers dying of acquired immune deficiency syndrome, or by parents incapable of providing adequate care;

(9) there is a need for comprehensive services for such infants and young children, including foster family care services, case management services, family support services, respite and crisis intervention services, counseling services, and group residential home services;

(10) there is a need to support the families of such infants and young children through the provision of services that will prevent the abandonment of the infants and children; and

¹ 42 U.S.C. 670 note.

(11) there is a need for the development of funding strategies that coordinate and make the optimal use of all private resources, and Federal, State, and local resources, to establish and maintain such services.

TITLE I—PROJECTS REGARDING ABANDONMENT OF INFANTS AND YOUNG CHILDREN IN HOSPITALS

SEC. 101. ESTABLISHMENT OF PROGRAM OF DEMONSTRATION PROJECTS.

(a) **IN GENERAL.**—The Secretary of Health and Human Services may make grants to public and nonprofit private entities for the purpose of developing, implementing, and operating projects to demonstrate methods—

(1) to prevent the abandonment of infants and young children, including the provision of services to members of the natural family for any condition that increases the probability of abandonment of an infant or young child;

(2) to identify and address the needs of abandoned infants and young children;

(3) to assist abandoned infants and young children to reside with their natural families or in foster care, as appropriate;

(4) to recruit, train, and retain foster families for abandoned infants and young children;

(5) to carry out residential care programs for abandoned infants and young children who are unable to reside with their families or to be placed in foster care;

(6) to carry out programs of respite care for families and foster families of infants and young children described in subsection (b);

(7) to recruit and train health and social services personnel to work with families, foster care families, and residential care programs for abandoned infants and young children; and

(8) to prevent the abandonment of infants and young children, and to care for the infants and young children who have been abandoned, through model programs providing health, educational, and social services at a single site in a geographic area in which a significant number of infants and young children described in subsection (b) reside (with special consideration given to applications from entities that will provide the services of the project through community-based organizations).

(b) **PRIORITY IN PROVISION OF SERVICES.**—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, in carrying out the purpose described in subsection (a) (other than with respect to paragraph (6) of such subsection), the applicant will give priority to abandoned infants and young children—

(1) who are infected with the human immunodeficiency virus or who have been perinatally exposed to the virus; or

(2) who have been perinatally exposed to a dangerous drug.

(c) **CASE PLAN WITH RESPECT TO FOSTER CARE.**—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, if the applicant expends the grant to carry out any program of providing care to infants and young children in foster homes or in other nonmedical residential settings away from their parents, the applicant will ensure that—

(1) a case plan of the type described in paragraph (1) of section 475 of the Social Security Act is developed for each such infant and young child (to the extent that such infant and young child is not otherwise covered by such a plan); and

(2) the program includes a case review system of the type described in paragraph (5) of such section (covering each such infant and young child who is not otherwise subject to such a system).

(d) **ADMINISTRATION OF GRANT.**—

(1) The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees—

(A) to use the funds provided under this section only for the purposes specified in the application submitted to, and approved by, the Secretary pursuant to subsection (e);

(B) to establish such fiscal control and fund accounting procedures as may be necessary to ensure proper disbursement and accounting of Federal funds paid to the applicant under this section;

(C) to report to the Secretary annually on the utilization, cost, and outcome of activities conducted, and services furnished, under this section; and

(D) that if, during the majority of the 180-day period preceding the date of the enactment of this Act, the applicant has carried out any program with respect to the care of abandoned infants and young children, the applicant will expend the grant only for the purpose of significantly expanding, in accordance with subsection (a), activities under such program above the level provided under such program during the majority of such period.

(2) Subject to the availability of amounts made available in appropriations Acts for the fiscal year involved, the duration of a grant under subsection (a) shall be for a period of 3 years, except that the Secretary—

(A) may terminate the grant if the Secretary determines that the entity involved has substantially failed to comply with the agreements required as a condition of the provision of the grant; and

(B) shall continue the grant for one additional year if the Secretary determines that the entity has satisfactorily complied with such agreements.

(e) **REQUIREMENT OF APPLICATION.**—The Secretary may not make a grant under subsection (a) unless—

(1) an application for the grant is submitted to the Secretary;

(2) with respect to carrying out the purpose for which the grant is to be made, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(f) **TECHNICAL ASSISTANCE TO GRANTEEES.**—The Secretary may, without charge to any grantee under subsection (a), provide technical assistance (including training) with respect to the planning, development, and operation of projects described in such subsection. The Secretary may provide such technical assistance directly, through contracts, or through grants.

(g) **TECHNICAL ASSISTANCE WITH RESPECT TO PROCESS OF APPLYING FOR GRANT.**—The Secretary may provide technical assistance (including training) to public and nonprofit private entities with respect to the process of applying to the Secretary for a grant under subsection (a). The Secretary may provide such technical assistance directly, through contracts, or through grants.

SEC. 102. EVALUATIONS, STUDIES, AND REPORTS BY SECRETARY.

(a) **EVALUATIONS OF DEMONSTRATION PROJECTS.**—The Secretary shall, directly or through contracts with public and nonprofit private entities, provide for evaluations of projects carried out under section 101 and for the dissemination of information developed as result of such projects.

(b) **DISSEMINATION OF INFORMATION TO INDIVIDUALS WITH SPECIAL NEEDS.**—

(1)(A) The Secretary may enter into contracts or cooperative agreements with public or nonprofit private entities for the development and operation of model projects to disseminate the information described in subparagraph (B) to individuals who are disproportionately at risk of dysfunctional behaviors that lead to the abandonment of infants or young children.

(B) The information referred to in subparagraph (A) is information on the availability to individuals described in such subparagraph, and the families of the individuals, of financial assistance and services under Federal, State, local, and private programs providing health services, mental health services, educational services, housing services, social services, or other appropriate services.

(2) The Secretary may not provide a contract or cooperative agreement under paragraph (1) to an entity unless—

(A) the entity has demonstrated expertise in the functions with respect to which such financial assistance is to be provided; and

(B) the entity agrees that in disseminating information on programs described in such paragraph, the entity will give priority—

(i) to providing the information to individuals described in such paragraph who—

(I) engage in the abuse of alcohol or drugs,
who are infected with the human

immunodeficiency virus, or who have limited proficiency in speaking the English language; or

(II) have been historically underserved in the provision of the information; and

(ii) to providing information on programs that are operated in the geographic area in which the individuals involved reside and that will assist in eliminating or reducing the extent of behaviors described in such paragraph.

(3) In providing contracts and cooperative agreements under paragraph (1), the Secretary may not provide more than 1 such contract or agreement with respect to any geographic area.

(4) Subject to the availability of amounts made available in appropriations Acts for the fiscal year involved, the duration of a contract or cooperative agreement under paragraph (1) shall be for a period of 3 years, except that the Secretary may terminate such financial assistance if the Secretary determines that the entity involved has substantially failed to comply with the agreements required as a condition of the provision of the assistance.

(c) STUDY AND REPORT ON NUMBER OF ABANDONED INFANTS AND YOUNG CHILDREN.—

(1) The Secretary shall conduct a study for the purpose of determining—

(A) an estimate of the number of infants and young children abandoned in hospitals in the United States and the number of such infants and young children who are infants and young children described in section 101(b); and

(B) an estimate of the annual costs incurred by the Federal Government and by State and local governments in providing housing and care for such infants and young children.

(2) Not later than April 1, 1992, the Secretary shall complete the study required in paragraph (1) and submit to the Congress a report describing the findings made as a result of the study.

(d) STUDY AND REPORT ON EFFECTIVE CARE METHODS.—

(1) The Secretary shall conduct a study for the purpose of determining the most effective methods for responding to the needs of abandoned infants and young children.

(2) The Secretary shall, not later than April 1, 1991, complete the study required in paragraph (1) and submit to the Congress a report describing the findings made as a result of the study.

SEC. 103. DEFINITIONS.

For purposes of this title:

(1) The terms “abandoned” and “abandonment”, with respect to infants and young children, mean that the infants and young children are medically cleared for discharge from acute-care hospital settings, but remain hospitalized because of a lack of appropriate out-of-hospital placement alternatives.

(2) The term "dangerous drug" means a controlled substance, as defined in section 102 of the Controlled Substances Act.

(3) The term "natural family" shall be broadly interpreted to include natural parents, grandparents, family members, guardians, children residing in the household, and individuals residing in the household on a continuing basis who are in a care-giving situation with respect to infants and young children covered under this Act.

SEC. 104. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—

(1) For the purpose of carrying out this title (other than section 102(b)), there are authorized to be appropriated \$20,000,000 for fiscal year 1992, \$25,000,000 for fiscal year 1993, \$30,000,000 for fiscal year 1994, and \$35,000,000 for fiscal year 1995.

(2)(A) Of the amounts appropriated under paragraph (1) for any fiscal year in excess of the amount appropriated under this subsection for fiscal year 1991, as adjusted in accordance with subparagraph (B), the Secretary shall make available not less than 50 percent for grants under section 101(a) to carry out projects described in paragraph (8) of such section.

(B) For purposes of subparagraph (A), the amount relating to fiscal year 1991 shall be adjusted for a fiscal year to a greater amount to the extent necessary to reflect the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with March of the preceding fiscal year.

(3) Not more than 5 percent of the amounts appropriate under paragraph (1) for any fiscal year may be obligated for carrying out section 102(a).

(b) DISSEMINATION OF INFORMATION FOR INDIVIDUALS WITH SPECIAL NEEDS.—For the purpose of carrying out section 102(b), there is authorized to be appropriated \$5,000,000 for each of the fiscal years 1992 through 1995.

(c) ADMINISTRATIVE EXPENSES.—

(1) For the purpose of the administration of this title by the Secretary, there is authorized to be appropriated for each fiscal year specified in subsection (a)(1) an amount equal to 5 percent of the amount authorized in such subsection to be appropriated for the fiscal year. With respect to the amounts appropriated under such subsection, the preceding sentence may not be construed to prohibit the expenditure of the amounts for the purpose described in such sentence.

(2) The Secretary may not obligate any of the amounts appropriated under paragraph (1) for a fiscal year unless, from the amounts appropriated under subsection (a)(1) for the fiscal year, the Secretary has obligated for the purpose described in such paragraph an amount equal to the amounts obligated by the Secretary for such purpose in fiscal year 1991.

(d) AVAILABILITY OF FUNDS.—Amounts appropriated under this section shall remain available until expended.

TITLE II—MEDICAL COSTS OF TREATMENT WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

SEC. 201. STUDY AND REPORT ON ASSISTANCE.

(a) **STUDY.**—The Secretary shall conduct a study for the purpose of—

(1) determining cost-effective methods for providing assistance to individuals for the medical costs of treatment of conditions arising from infection with the etiologic agent for acquired immune deficiency syndrome, including determining the feasibility of risk-pool health insurance for individuals at risk of such infection;

(2) determining the extent to which Federal payments under title XIX of the Social Security Act are being expended for medical costs described in paragraph (1); and

(3) providing an estimate of the extent to which such Federal payments will be expended for such medical costs during the 5-year period beginning on the date of the enactment of this Act.

(b) **REPORT.**—The Secretary shall, not later than 12 months after the date of the enactment of this Act, complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study.

TITLE III—GENERAL PROVISIONS

SEC. 301. DEFINITIONS.

For purposes of this Act:

(1) The term “acquired immune deficiency syndrome” includes infection with the etiologic agent for such syndrome, any condition indicating that an individual is infected with such etiologic agent, and any condition arising from such etiologic agent.

(2) The term “Secretary” means the Secretary of Health and Human Services.

MISCELLANEOUS PROVISIONS



**MISCELLANEOUS PROVISION RELATING TO
AVAILABILITY OF APPROPRIATIONS**

MISCELLANEOUS PROVISION RELATING TO AVAILABILITY OF APPROPRIATIONS

SECTION 601 OF PUBLIC LAW 91-296

TITLE VI—AVAILABILITY OF APPROPRIATIONS

SEC. 601. Notwithstanding any other provision of law, unless enacted after the enactment of this Act expressly in limitation of the provisions of this section, funds appropriated for any fiscal year to carry out any program for which appropriations are authorized by the Public Health Service Act (Public Law 410, Seventy-eighth Congress, as amended) or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963 (Public Law 88-164, as amended) shall remain available for obligation and expenditure until the end of such fiscal year.

LEGISLATIVE HISTORY

House Reports: No. 91-262 (Comm. on Interstate and Foreign Commerce) and No. 91-1167 (Comm. of Conference).

Senate Report No. 91-657 (Comm. on Labor and Public Welfare).

Congressional Record:

Vol. 115 (1969): June 4, considered and passed House.

Vol. 116 (1970):

Apr. 7, considered and passed Senate, amended.

June 8, Senate agreed to conference report.

June 10, House agreed to conference report.

June 22, vetoed.

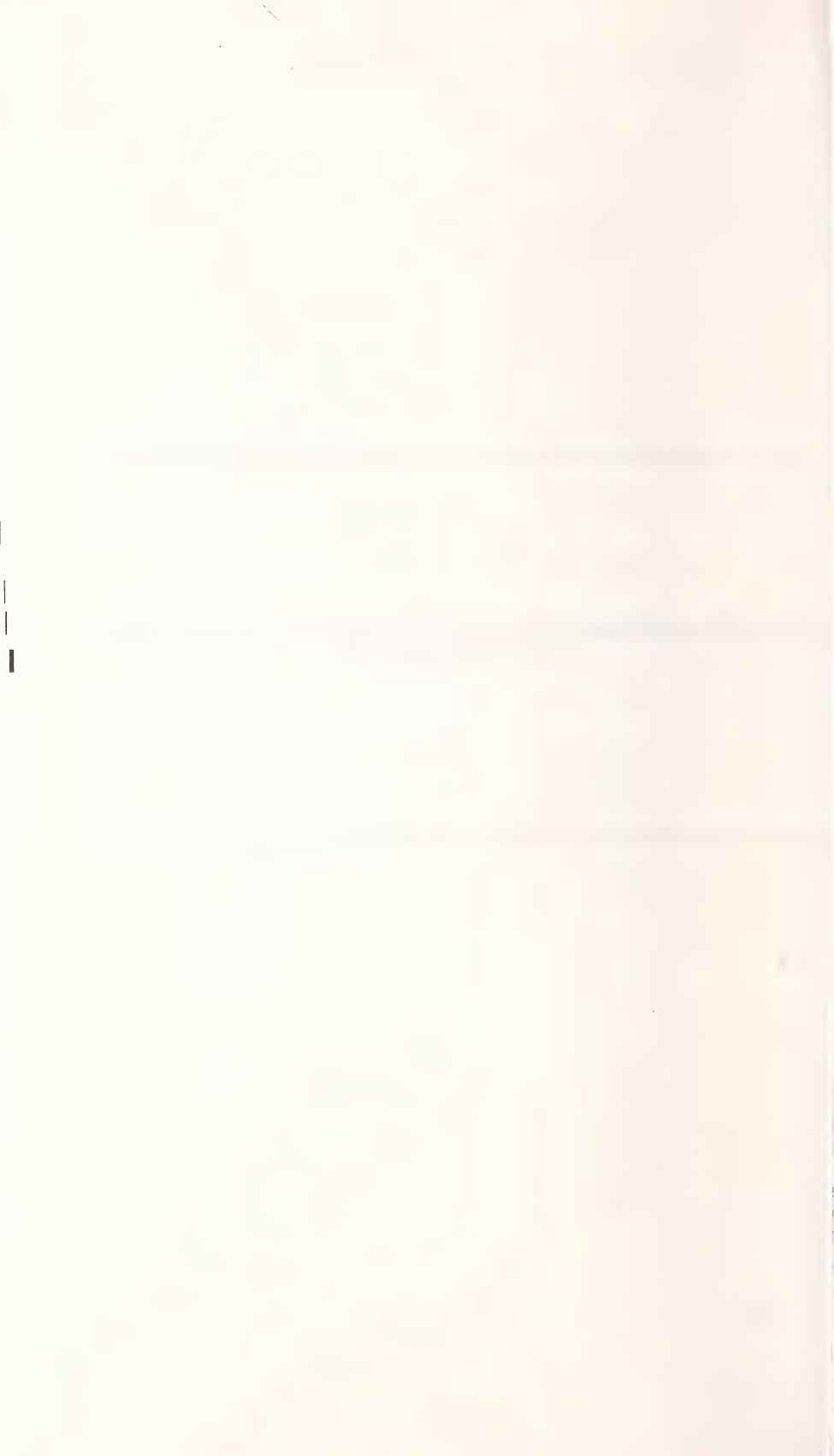
June 25, passed House over veto.

June 30, passed Senate over veto.

Amended by Section 401(a) of P.L. 93-45 and Section 113 of P.L. 93-352.



**MISCELLANEOUS PROVISIONS RELATING TO ALCOHOL
AND TREATMENT**



MISCELLANEOUS PROVISIONS RELATING TO ALCOHOL AND TREATMENT

COMPREHENSIVE ALCOHOL ABUSE AND ALCOHOLISM PREVENTION, TREATMENT, AND REHABILITATION ACT OF 1974¹

(References in black brackets [] are to title 42, United States Code)

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TITLE III—TECHNICAL ASSISTANCE AND FEDERAL GRANTS AND CONTRACTS

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PART B—PROJECTS GRANTS AND CONTRACTS

GRANTS AND CONTRACTS FOR THE DEMONSTRATION OF NEW AND MORE EFFECTIVE ALCOHOL ABUSE AND ALCOHOLISM PREVENTION, TREATMENT, AND REHABILITATION PROGRAMS

SEC. 311. [4577] (a) The Secretary, acting through the Institute, may make grants to public and nonprofit private entities and may enter into contracts with public and private entities and with individuals—

(1) to conduct demonstration and evaluation projects, with a high priority on prevention and early intervention projects in occupational and educational settings and on modified community living and work-care arrangements such as halfway houses, recovery homes, and supervised home care, and with particular emphasis on developing new and more effective alcohol abuse and alcoholism prevention, treatment, and rehabilitation programs,

(2) to support projects of a demonstration value in developing methods for the effective coordination of all alcoholism treatment, training, prevention, and research resources available within a health service area established under section 1511 of the Public Health Service Act, and

(3) to provide education and training, which may include additional training to enable treatment personnel to meet certification requirements of public or private accreditation or licensure, or requirements of third-party payors, for the prevention and treatment of alcohol abuse and alcoholism and for the rehabilitation of alcohol abusers and alcoholics.

(b) Projects and programs for which grants and contracts are made under this section shall (1) be responsive to special requirements of handicapped individuals in receiving such services; (2) whenever possible, be community based, seek (in the case of pre-

¹ Public Law 91-616.

vention and treatment services) to insure care of good quality in general community care facilities and under health insurance plans, and be integrated with, and provide for the active participation of, a wide range of public and nongovernmental agencies, organizations, institutions, and individuals; (3) where a substantial number of the individuals in the population served by the project or program are of limited English-speaking ability, utilize the services of outreach workers fluent in the language spoken by a predominant number of such individuals and develop a plan and make arrangements responsive to the needs of such population for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and identify an individual employed by the project or program, or who is available to the project or program on a full-time basis, who is fluent both in that language and English and whose responsibilities shall include providing guidance to the individuals of limited English-speaking ability and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences; and (4) where appropriate utilize existing community resources (including community mental health centers).

(c)(1) In administering this section, the Secretary shall require coordination of all applications for projects and programs in a State.

(2)(A) Each applicant from within a State, upon filing its application with the Secretary for a grant or contract under this section, shall submit a copy of its application for review by the State agency responsible for the administration of alcohol abuse and alcoholism prevention, treatment, and rehabilitation activities. Such State agency shall be given not more than thirty days from the date of receipt of the application to submit to the Secretary, in writing, an evaluation of the project or program set forth in the application. Such evaluation shall include comments on the relationship of the project to other projects and programs pending and approved and to any State comprehensive plan for treatment and prevention of alcohol abuse and alcoholism. The State shall furnish the applicant a copy of any such evaluation.

(B)(i) Except as provided in clause (ii), each application for a grant under this section shall be submitted by the Secretary to the National Advisory Council on Alcohol Abuse and Alcoholism for its review. The Secretary may approve an application for a grant under this section only if it is recommended for approval by such Council.

(ii) Clause (i) shall not apply to an application for a grant under this section for a project or program for any period of 12 consecutive months for which period payments under such grant will be less than \$250,000, if an application for a grant under this section for such project or program and for a period of time which includes such 12-month period has been submitted to, and approved by, the Secretary.

(3) Approval of any application for a grant or contract by the Secretary, including the earmarking or financial assistance for a program or project, may be granted only if the application substantially meets a set of criteria established by the Secretary that—

(A) provides that the projects and programs for which assistance under this section is sought will be substantially administered by or under the supervision of the applicant;

(B) provides for such methods of administration as are necessary for the proper and efficient operation of such programs and projects; and

(C) provides for such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for Federal funds paid to the applicant.

(4) The Secretary shall encourage the submission of and give special consideration to applications under this section for programs and projects aimed at underserved populations such as racial and ethnic minorities, Native Americans (including Native Hawaiians and Native American Pacific Islanders), youth, the elderly, women, handicapped individuals, public inebriates, and families of alcoholics.

(5)(A) No grant may be made under this section to a State or to any entity within the government of a State unless the grant application has been duly authorized by the chief executive officer of such State.

(B) No grant or contract may be made under this section for a period in excess of five years.

(C)(i) The amount of any grant or contract under this section may not exceed 100 per centum of the cost of carrying out the grant or contract in the first fiscal year for which the grant or contract is made under this section, 80 per centum of such cost in the second fiscal year for which the grant or contract is made under this section, 70 per centum of such cost in the third fiscal year for which the grant or contract is made under this section, and 60 per centum of such cost in each of the fourth and fifth fiscal years for which the grant or contract is made under this section.

(ii) For purposes of this subparagraph, no grant or contract shall be considered to have been made under this section for a fiscal year ending before September 30, 1981.

(6) Each applicant, upon filing its application with the Secretary for a grant or contract to provide prevention or treatment services, shall provide a proposed performance standard or standards to measure, or research protocol to determine, the effectiveness of such services.

(7) Nothing shall prevent the use of funds provided under this section for programs and projects aimed at the prevention, treatment, or rehabilitation of drug abuse as well as alcohol abuse and alcoholism.

AUTHORIZATIONS OF APPROPRIATIONS

SEC. 312. [4578] For purposes of section 311, there are authorized to be appropriated \$85,000,000 for the fiscal year ending September 30, 1977, \$91,000,000 for the fiscal year ending September 30, 1978, and \$102,500,000 for the fiscal year ending September 30, 1979, \$102,500,000 for the fiscal year ending September 30, 1980, \$115,000,000 for the fiscal year ending September 30, 1981, and \$15,000,000 for the fiscal year ending September 30, 1982. Of the funds appropriated under this section for the fiscal year ending

September 30, 1980, at least 8 percent of the funds shall be obligated for grants for projects, programs, and services to prevent (through outreach, intervention, and education) the occurrence of alcoholism and alcohol abuse; of the funds appropriated under this section for the next fiscal year at least 10 percent of the funds shall be obligated for such grants and of the funds appropriated under this section for the fiscal year ending September 30, 1982, at least 25 per centum of the funds shall be obligated for such grants.

SEC. 334. (a) Not later than June 1, 1980, the Secretary of Health, Education, and Welfare, acting through the Assistant Secretary for Health, and the Secretary of the Treasury, acting through the Assistant Secretary for Enforcement and Operations, shall jointly report to the President and the Congress—

(1) the extent and nature of birth defects associated with alcohol consumption by pregnant women,

(2) the extent and nature of other health hazards associated with alcoholic beverages, and

(3) the actions which should be taken by the Federal Government under the Federal Alcohol Administration Act and the Federal Food, Drug, and Cosmetic Act with respect to informing the general public of such health hazards.

(b) Subsection (a) shall not be construed to limit the authority of the Attorney General, the Secretary of the Treasury, or the Secretary of Health, Education, and Welfare under the Federal Alcohol Administration Act or the Federal Food, Drug, and Cosmetic Act.

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TITLE VI—GENERAL

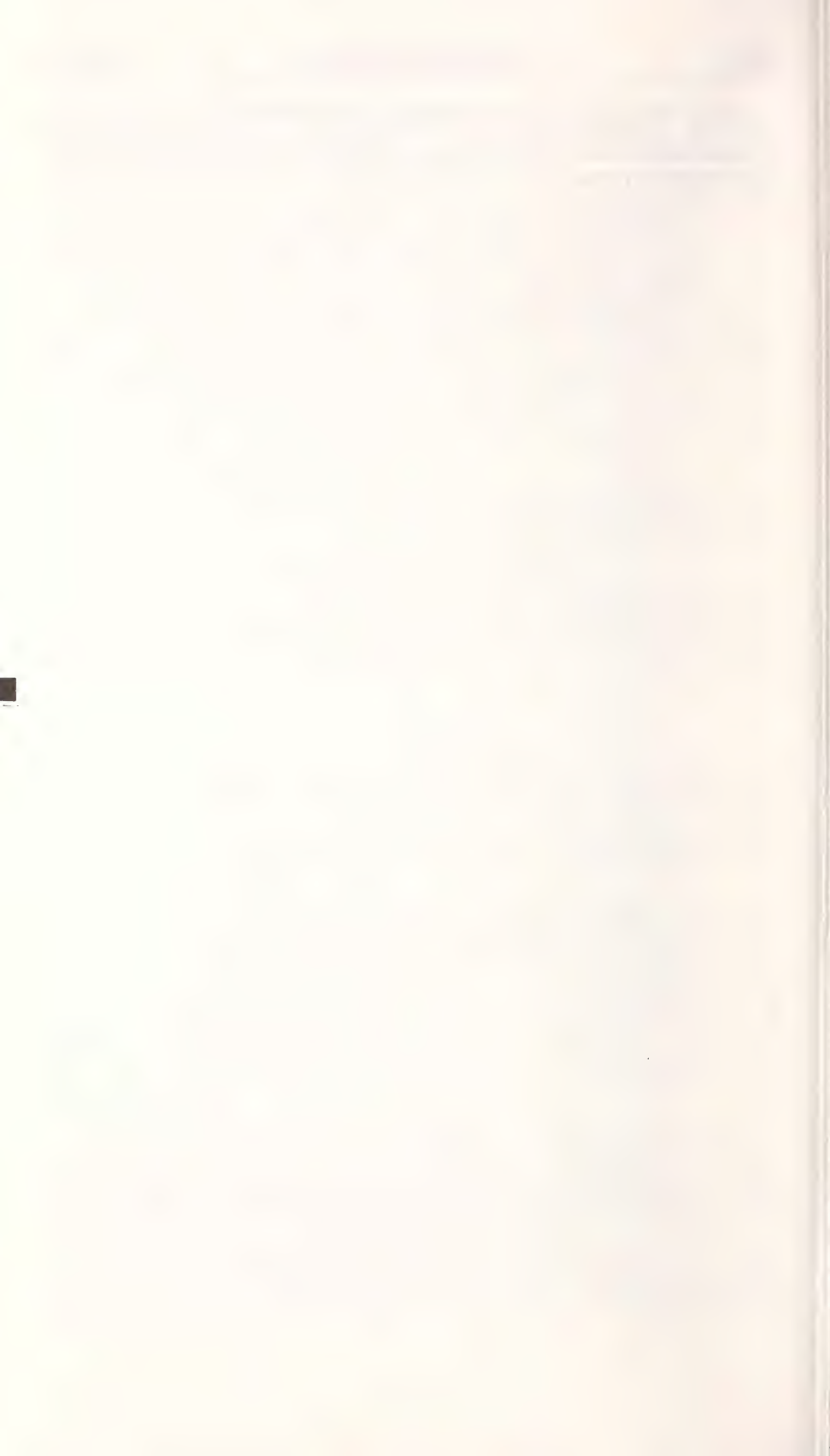
SEC. 601. [4591] If any section, provision, or term of this Act is adjudged invalid for any reason, such judgment shall not affect, impair, or invalidate any other section, provision, or term of this Act, and the remaining sections, provisions, and terms shall be and remain in full force and effect.

SEC. 602. [4592] (a) Each recipient of assistance under this Act pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant or contract, the total cost of the project or undertaking in connection with which such grant or contract is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(b) The Secretary and Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to the grants or contracts entered into under the provisions of this Act under other than competitive bidding procedures.

SEC. 603. [4593] Payments under this Act may be made in advance or by way of reimbursement and in such installments as the Secretary may determine.

SEC. 604. [4594] The authority of the Secretary to enter into contracts under this Act shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.



**MISCELLANEOUS PROVISIONS RELATING TO ADVISORY
COMMITTEES**



MISCELLANEOUS PROVISIONS RELATING TO ADVISORY COMMITTEES

TITLE X OF PUBLIC LAW 94-278

TITLE X—APPOINTMENT OF ADVISORY COMMITTEES

SEC. 1001. All appointments to advisory committees established to assist in implementing the Public Health Service Act, the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, shall be made without regard to political affiliation.

LEGISLATIVE HISTORY

House Reports: No. 94-498 (Committee on Interstate and Foreign Commerce) and No. 94-1005 (Committee of Conference).

Senate Reports: No. 94-509 accompanying S. 988 (Committee on Labor and Public Welfare) and No. 94-743 (Committee of Conference).

Congressional Record:

Vol. 121 (1975):

Oct. 20, considered and passed House.

Dec. 11, considered and passed Senate, amended, in lieu of S. 988.

Vol. 122 (1976):

Apr. 12, House and Senate agreed to conference report.

FEDERAL ADVISORY COMMITTEE ACT¹

FINDINGS AND PURPOSES

SEC. 2. (a) The Congress finds that there are numerous committees, boards, commissions, councils, and similar groups which have been established to advise officers and agencies in the executive branch of the Federal Government and that they are frequently a useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the Federal Government.

(b) The Congress further finds and declares that—

(1) the need for many existing advisory committees has not been adequately reviewed;

(2) new advisory committees should be established only when they are determined to be essential and their number should be kept to the minimum necessary;

(3) advisory committees should be terminated when they are no longer carrying out the purposes for which they were established;

(4) standards and uniform procedures should govern the establishment, operation, administration, and duration of advisory committees;

¹ Public Law 92-463, whose first section established the above short title.

(5) the Congress and the public should be kept informed with respect to the number, purpose, membership, activities, and cost of advisory committees; and

(6) the function of advisory committees should be advisory only, and that all matters under their consideration should be determined, in accordance with law, by the official, agency, or officer involved.

DEFINITIONS

SEC. 3. For the purpose of this Act—

(1) The term "Director" means the Director of the Office of Management and Budget.

(2) The term "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee"), which is—

(A) established by statute or reorganization plan, or

(B) established or utilized by the "President, or

(C) established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government, except that such term excludes (i) the Advisory Commission on Intergovernmental Relations, (ii) the Commission on Government Procurement, and (iii) any committee which is composed wholly of full-time officers or employees of the Federal Government.

(3) The term "agency" has the same meaning as in section 551(1) of title 5, United States Code.

(4) The term "Presidential advisory committee" means an advisory committee which advises the President.

APPLICABILITY

SEC. 4. (a) The provisions of this Act or of any rule, order, or regulation promulgated under this Act shall apply to each advisory committee except to the extent that any Act of Congress establishing any such advisory committee specifically provides otherwise.

(b) Nothing in this Act shall be construed to apply to any advisory committee established or utilized by—

(1) the Central Intelligence Agency; or

(2) the Federal Reserve System.

(c) Nothing in this Act shall be construed to apply to any local civic group whose primary function is that of rendering a public service with respect to a Federal program, or any State or local committee, council, board, commission, or similar group established to advise or make recommendations to State or local officials or agencies.

RESPONSIBILITIES OF CONGRESSIONAL COMMITTEES

SEC. 5. (a) In the exercise of its legislative review function, each standing committee of the Senate and the House of Representatives shall make a continuing review of the activities of each advisory committee under its jurisdiction to determine wheth-

er such advisory committee should be abolished or merged with any other advisory committee, whether the responsibilities of such advisory committee should be revised, and whether such advisory committee performs a necessary function not already being performed. Each such standing committee shall take appropriate action to obtain the enactment of legislation necessary to carry out the purpose of this subsection.

(b) In considering legislation establishing, or authorizing the establishment of any advisory committee, each standing committee of the Senate and of the House of Representatives shall determine, and report such determination to the Senate or to the House of Representatives, as the case may be, whether the functions of the proposed advisory committee are being or could be performed by one or more agencies or by an advisory committee already in existence, or by enlarging the mandate of an existing advisory committee. Any such legislation shall—

(1) contain a clearly defined purpose for the advisory committee;

(2) require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;

(3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment;

(4) contain provisions dealing with authorization of appropriations, the date for submission of reports (if any), the duration of the advisory committee, and the publication of reports and other materials, to the extent that the standing committee determines the provisions of section 10 of this Act to be inadequate; and

(5) contain provisions which will assure that the advisory committee will have adequate staff (either supplied by an agency or employed by it), will be provided adequate quarters, and will have funds available to meet its other necessary expenses.

(c) To the extent they are applicable, the guidelines set out in subsection (b) of this section shall be followed by the President, agency, heads, or other Federal officials in creating an advisory committee.

RESPONSIBILITIES OF THE PRESIDENT

SEC. 6. (a) The President may delegate responsibility for evaluating and taking action, where appropriate, with respect to all public recommendations made to him by Presidential advisory committees.

(b) Within one year after a Presidential advisory committee has submitted a public report to the President, the President or his delegate shall make a report to the Congress stating either his proposals for action or his reasons for inaction, with respect to the recommendations contained in the public report.

(c) The President shall, not later than December 31 of each year, make an annual report to the Congress on the activities, sta-

tus, and changes in the composition of advisory committees in existence during the preceding fiscal year. The report shall contain the name of every advisory committee, the date of and authority for its creation, its termination date or the date it is to make a report, its functions, a reference to the reports it has submitted, a statement of whether it is an ad hoc or continuing body, the dates of its meetings, the names and occupations of its current members, and the total estimated annual cost to the United States to fund, service, supply, and maintain such committee. Such report shall include a list of those advisory committees abolished by the President, and in the case of advisory committees established by statute, a list of those advisory committees which the President recommends be abolished together with his reasons therefor. The President shall exclude from this report any information which, in his judgment, should be withheld for reasons of national security, and he shall include in such report a statement that such information is excluded.

RESPONSIBILITIES OF THE DIRECTOR, OFFICE OF MANAGEMENT AND
BUDGET

SEC. 7. (a) The Director shall establish and maintain within the Office of Management and Budget a Committee Management Secretariat, which shall be responsible for all matters relating to advisory committees.

(b) The Director shall, immediately after the enactment of this Act, institute a comprehensive review of the activities and responsibilities of each advisory committee to determine—

- (1) whether such committee is carrying out its purpose;
- (2) whether, consistent with the provisions of applicable statutes, the responsibilities assigned to it should be revised;
- (3) whether it should be merged with other advisory committees; or
- (4) whether it should be abolished.

The Director may from time to time request such information as he deems necessary to carry out his functions under this subsection. Upon the completion of the Director's review he shall make recommendations to the President and to either the agency head or the Congress with respect to action he believes should be taken. Thereafter, the Director shall carry out a similar review annually. Agency heads shall cooperate with the Director in making the required by this subsection.

(c) The Director shall prescribe administrative guidelines and management controls applicable to advisory committees, and, to the maximum extent feasible, provide advice, assistance, and guidance to advisory committees to improve their performance. In carrying out his functions under this subsection, the Director shall consider the recommendations of each agency head with respect to means of improving the performance of advisory committees whose duties are related to such agency.

(d)(1) The Director, after study and consultation with the Civil Service Commission, shall establish guidelines with respect to uniform fair rates of pay for comparable services of members, staffs, and consultants of advisory committees in a manner which gives appropriate recognition to the responsibilities and qualifications re-

quired and other relevant factors. Such regulations shall provide that—

(A) no member of any advisory committee or of the staff of any advisory committee shall receive compensation at a rate in excess of the rate specified for GS-18 of the General Schedule under section 5332 of title 5, United States Code;

(B) such members, while engaged in the performance of their duties away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons employed intermittently in the Government service; and

(C) such members—

(i) who are blind or deaf or who otherwise qualify as handicapped individuals (within the meaning of section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 794)), and

(ii) who do not otherwise qualify for assistance under section 3102 of title 5, United States Code, by reason of being an employee of an agency (within the meaning of section 3102(a)(1) of such title 5),

may be provided services pursuant to section 3102 of such title 5 while in performance of their advisory committee duties.

(2) Nothing in this subsection shall prevent—

(A) an individual who (without regard to his service with an advisory committee) is a full-time employee of the United States, or

(B) an individual who immediately before his service with an advisory committee was such an employee, from receiving compensation at the rate at which he otherwise would be compensated (or was compensated) as a full-time employee of the United States.

(e) The Director shall include in budget recommendations a summary of the amounts he deems necessary for the expenses of advisory committees, including the expenses for publication of reports where appropriate.

RESPONSIBILITIES OF AGENCY HEADS

SEC. 8. (a) Each agency head shall establish uniform administrative guidelines and management controls for advisory committees established by that agency, which shall be consistent with directives of the Director under section 7 and section 10. Each agency shall maintain systematic information on the nature, functions, and operations of each advisory committee within its jurisdiction.

(b) The head of each agency which has an advisory committee shall designate an Advisory Committee Management Officer who shall—

(1) exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by that agency;

(2) assemble and maintain the reports, records, and other papers of any such committee during its existence; and

(3) carry out, on behalf of that agency, the provisions of section 552 of title 5, United States Code, with respect to such reports, records, and other papers.

ESTABLISHMENT AND PURPOSE OF ADVISORY COMMITTEES

SEC. 9. (a) No advisory committee shall be established unless such establishment is—

(1) specifically authorized by statute or by the President; or

(2) determined as a matter of formal record, by the head of the agency involved after consultation with the Director, with timely notice published in the Federal Register, to be in the public interest in connection with the performance of duties imposed on that agency by law.

(b) Unless otherwise specifically provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. Determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations shall be made solely by the President or an officer of the Federal Government.

(c) No advisory committee shall meet or take any action until an advisory committee charter has been filed with (1) the Director, in the case of Presidential advisory committees, or (2) with the head of the agency to whom any advisory committee reports and with the standing committees of the Senate and of the House of Representatives having legislative jurisdiction of such agency. Such charter shall contain the following information:

(A) the committee's official designation;

(B) the committee's objectives and the scope of its activity;

(C) the period of time necessary for the committee to carry out its purposes;

(D) the agency or official to whom the committee reports;

(E) the agency responsible for providing the necessary support for the committee;

(F) a description of the duties for which the committee is responsible, and, if such duties are not solely advisory, a specification of the authority for such functions;

(G) the estimated annual operating costs in dollars and man-years for such committee;

(H) the estimated number and frequency of committee meetings;

(I) the committee's termination date, if less than two years from the date of the committee's establishment; and

(J) the date the charter is filed.

A copy of any such charter shall also be furnished to the Library of Congress.

ADVISORY COMMITTEE PROCEDURES

SEC. 10. (a)(1) Each advisory committee meeting shall be open to the public.

(2) Except when the President determines otherwise for reasons of national security, timely notice of each such meeting shall be published in the Federal Register, and the Director shall prescribe regulations to provide for other types of public notice to insure that all interested persons are notified of such meeting prior thereto.

(3) Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Director may prescribe.

(b) Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

(c) Detailed minutes of each meeting of each advisory committee shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the advisory committee. The accuracy of all minutes shall be certified to by the chairman of the advisory committee.

(d) Subsections (a)(1) and (a)(3) of this section shall not apply to any portion of an advisory committee meeting where the President, or the head of the agency to which the advisory committee reports, determines that such portion of such meeting may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code. Any such determination shall be in writing and shall contain the reasons for such determination. If such a determination is made, the advisory committee shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of section 552(b) of title 5, United States Code.

(e) There shall be designated an officer or employee of the Federal Government to chair or attend each meeting of each advisory committee. The officer or employee so designated is authorized whenever he determines it to be in the public interest, to adjourn any such meeting. No advisory committee shall conduct any meeting in the absence of that officer or employee.

(f) Advisory committees shall not hold any meetings except at the call of, or with the advance approval of, a designated officer or employee of the Federal Government, and in the case of advisory committees (other than Presidential advisory committees), with an agenda approved by such officer or employee.

AVAILABILITY OF TRANSCRIPTS

SEC. 11. (a) Except where prohibited by contractual agreements entered into prior to the effective date of this Act, agencies and advisory committees shall make available to any person, at actual cost of duplication, copies of transcripts of agency proceedings or advisory committee meetings.

(b) As used in this section "agency proceeding" means any proceeding as defined in section 551(12) of title 5, United States Code.

FISCAL AND ADMINISTRATIVE PROVISIONS

SEC. 12. (a) Each agency shall keep records as will fully disclose the disposition of any funds which may be at the disposal of

its advisory committees and the nature and extent of their activities. The General Services Administration, or such other agency as the President may designate, shall maintain financial records with respect to Presidential advisory committees. The Comptroller General of the United States, or any of his authorized representatives, shall have access, for the purpose of audit and examination, to any such records.

(b) Each agency shall be responsible for providing support services for each advisory committee established by or reporting to it unless the establishing authority provides otherwise. Where any such advisory committee reports to more than one agency, only one agency shall be responsible for support services at any one time. In the case of Presidential advisory committees, such services may be provided by the General Services Administration.

RESPONSIBILITIES OF LIBRARY OF CONGRESS

SEC. 13. Subject to section 552 of title 5, United States Code, the Director shall provide for the filing with the Library of Congress of at least eight copies of each report made by every advisory committee and, where appropriate, background papers prepared by consultants. The Librarian of Congress shall establish a depository for such reports and papers where they shall be available to public inspection and use.

TERMINATION OF ADVISORY COMMITTEES

SEC. 14. (a)(1) Each advisory committee which is in existence on the effective date of this Act shall terminate not later than the expiration of the two-year period following such effective date unless—

(A) in the case of an advisory committee established by the President or an officer of the Federal Government, such advisory committee is renewed by the President or that officer by a appropriate action prior to the expiration of such two-year period; or

(B) in the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

(2) Each advisory committee established after such effective date shall terminate not later than the expiration of the two-year period beginning on the date of its establishment unless—

(A) in the case of an advisory committee established by the President or an officer of the Federal Government such advisory committee is renewed by the President or such officer by appropriate action prior to the end of such period; or

(B) in the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

(b)(1) Upon the renewal of any advisory committee, such advisory committee shall file a charter in accordance with section 9(c).

(2) Any advisory committee established by an Act of Congress shall file a charter in accordance with such section upon the expiration of each successive two-year period following the date of enactment of the Act establishing such advisory committee.

(3) No advisory committee required under this subsection to file a charter shall take any action (other than preparation and filing of such charter) prior to the date on which such charter is filed.

(c) Any advisory committee which is renewed by the President or any officer of the Federal Government may be continued only for successive two-year periods by appropriate action taken by the President or such officer prior to the date on which such advisory committee would otherwise terminate.

EFFECTIVE DATE

SEC. 15. Except as provided in section 7(b), this Act shall become effective upon the expiration of ninety days following the date of enactment.

LEGISLATIVE HISTORY

House Reports: No. 92-1017 (Committee on Government Operations) and No. 92-1403 (Committee of Conference).

Senate Report No. 92-1098 accompanying S. 3529 (Committee on Government Operations).

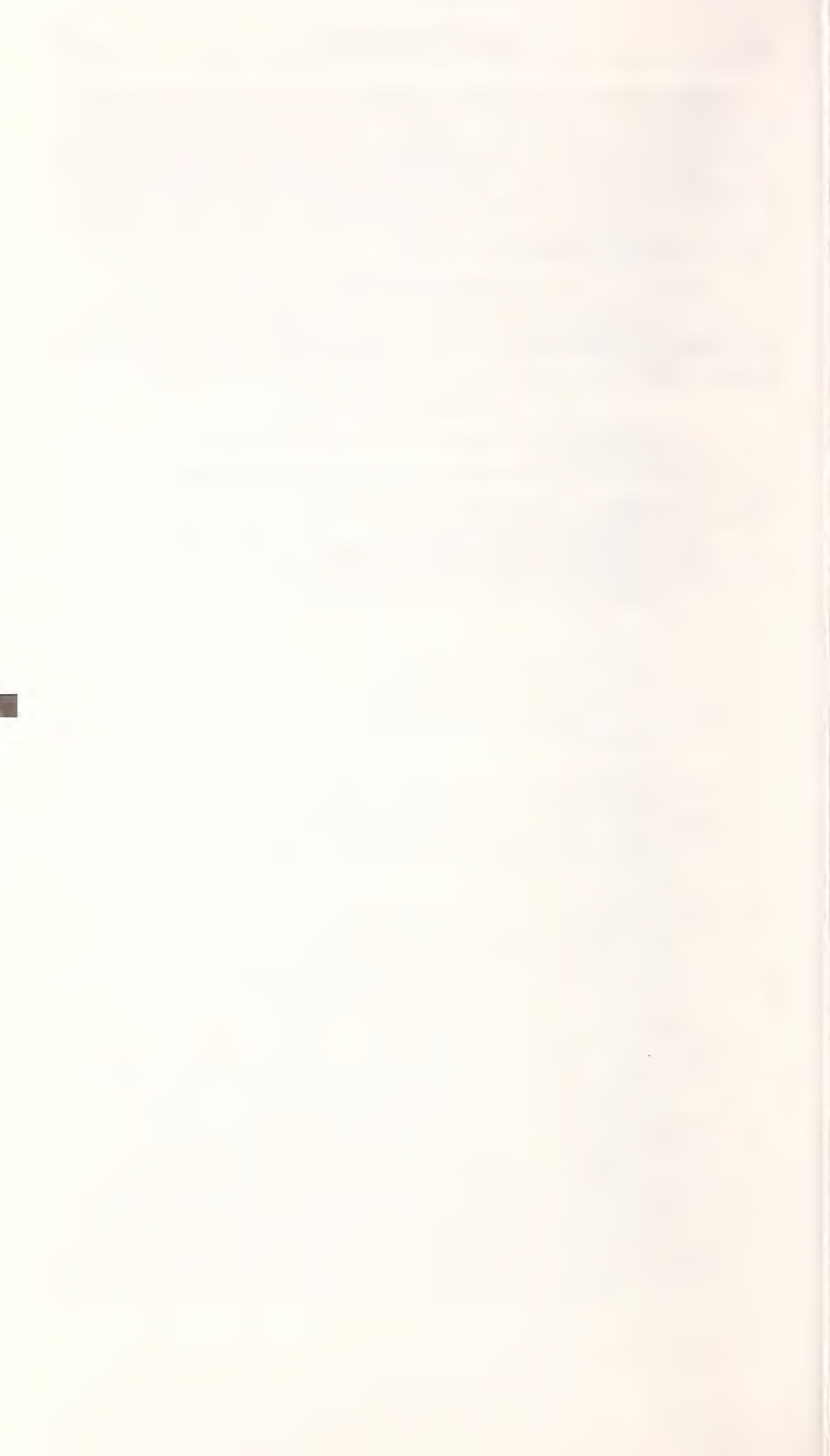
Congressional Record, vol. 118 (1972):

May 9, considered and passed House.

Sept. 12, considered and passed Senate, amended, in lieu of S. 3529.

Sept. 19, Senate agreed to conference report.

Sept. 20, House agreed to conference report.



**MISCELLANEOUS PROVISIONS RELATING TO
ABORTIONS (ANTI-COERCION)**

MISCELLANEOUS PROVISIONS RELATING TO ABORTIONS (ANTI-COERCION)

SECTION 401 OF PUBLIC LAW 93-45¹

MISCELLANEOUS

SEC. 401. (a) * * *

(b) The receipt of any grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Development Disabilities Services and Facilities Construction Act by any individual or entity does not authorize any court or any public official or other public authority to require—

(1) such individual to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions; or

(2) such entity to—

(A) make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or

(B) provide any personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedure or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.

(c)(1) No entity which receives a grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Development Disabilities Services and Facilities Construction Act after the date of enactment of this Act may—

(A) discriminate in the employment, promotion, or termination of employment of any physician or other health care personnel, or

(B) discriminate in the extension of staff or other privileges to any physician or other health care personnel, because he performed or assisted in the performance of a lawful sterilization procedure or abortion, because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs

¹Section 401 was amended by section 214 of Public Law 93-348.

or moral convictions or because of his religious beliefs or moral convictions respecting sterilization procedures or abortions.

(2) No entity which receives after the date of enactment of this paragraph a grant or contract for biomedical or behavioral research under any program administered by the Secretary of Health, Education, and Welfare may—

(A) discriminate in the employment, promotion, or termination of employment of any physician or other health care personnel, or

(B) discriminate in the extension of staff or other privileges to any physician or other health care personnel, because he performed or assisted in the performance of any lawful health service or research activity, because he refused to perform or assist in the performance of any such service or activity on the grounds that his performance or assistance in the performance of such service or activity would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting any such service or activity.

(d) No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health, Education, and Welfare if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.

(e) No entity which receives, after the date of enactment of this paragraph, any grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Assistance and Bill of Rights Act may deny admission or otherwise discriminate against any applicant (including applicants for internships and residencies) for training or study because of the applicant's reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant's religious beliefs or moral convictions.

LEGISLATIVE HISTORY OF PUBLIC LAW 93-45

House Report No. 93-227 accompanying H.R. 7806 (Committee on Interstate and Foreign Commerce).

Senate Report No. 93-87 (Committee on Labor and Public Welfare).

Congressional Record, Vol. 119 (1973):

Mar. 13, 27, considered and passed Senate.

May 31, considered and passed House, amended, in lieu of H.R. 7806.

June 5, Senate concurred in House amendments.

LEGISLATIVE HISTORY OF PUBLIC LAW 93-348

House Reports: No. 93-224 (Committee on Interstate and Foreign Commerce) and No. 93-1148 (Committee of Conference).

Senate Report No. 93-381 (Committee on Labor and Public Welfare).

Congressional Record:

Vol. 119 (1973):

May 31, considered and passed House.

Sept. 11, considered and passed Senate, amended.

Vol. 120 (1974):

June 27, Senate agreed to conference report.

June 28, House agreed to conference report.

SECTION 205 OF PUBLIC LAW 94-63

SEC. 205. Any—

(1) officer or employee of the United States,

(2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or

(3) person who receives, under any program receiving Federal financial assistance, compensation for services,

who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than \$1,000 or imprisoned for not more than one year, or both.

LEGISLATIVE HISTORY

House Reports: No. 94-137 accompanying H.R. 4925, No. 94-143 accompanying H.R. 4115, and No. 94-192 accompanying H.R. 4114 (Committee on Interstate and Foreign Commerce) and No. 94-348 (Committee of Conference).

Senate Report No. 94-29 (Committee on Labor and Public Welfare).

Congressional Record, Vol. 121 (1975):

Apr. 10, considered and passed Senate.

May 7, H.R. 4114 and 4115 considered and passed House.

June 5, considered and passed House, amended, in lieu of H.R. 4114, H.R. 4115, and H.R. 4925.

July 14, Senate agreed to conference report.

July 16, House agreed to conference report.

Weekly Compilation of Presidential Documents, Vol. 11, No. 31: July 26, vetoed; Presidential message.

Congressional Record, Vol. 121 (1975):

July 26, Senate overrode veto.

July 29, House overrode veto.



**MISCELLANEOUS PROVISIONS RELATING TO ORPHAN
DRUGS**

MISCELLANEOUS PROVISIONS RELATING TO ORPHAN DRUGS

Section 5 OF THE ORPHAN DRUG ACT ¹

GRANTS AND CONTRACTS FOR DEVELOPMENT OF DRUGS FOR RARE DISEASES AND CONDITIONS

SEC. 5. (a) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in (1) defraying the cost of qualified testing expenses incurred in connection with the development of drugs for rare diseases and conditions, (2) defraying the costs of developing medical devices for rare diseases or conditions, and (3) defraying the costs of developing medical foods for rare diseases or conditions.

(b) For purposes of subsection (a):

(1) The term "qualified testing" means—

(A) human clinical testing—

(i) which is carried out under an exemption for a drug for a rare disease or condition under section 505(i) of the Federal Food, Drug, and Cosmetic Act (or regulations issued under such section); and

(ii) which occurs after the date such drug is designated under section 526 of such Act and before the date on which an application with respect to such drug is submitted under section 505(b) or 507 of such Act or under section 351 of the Public Health Service Act; and

(B) preclinical testing involving a drug for a rare disease or condition which occurs after the date such drug is designated under section 526 of such Act and before the date on which an application with respect to such drug is submitted under section 505(b) or 507 of such Act or under section 351 of the Public Health Service Act.

(2) The term "rare disease or condition" means (1) in the case of a drug, any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug, (2) in the case of a medical device, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical device for such disease or condition will be developed without assistance under subsection (a), and (3) in the case of a medical food, any dis-

¹ Public Law 97-414; 21 U.S.C. 360ee.

ease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical food for such disease or condition will be developed without assistance under subsection (a). Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under section 526 of the Federal Food, Drug, and Cosmetic Act is made.

(3) The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

(c) For grants and contracts under subsection (a) there are authorized to be appropriated \$10,000,000 for fiscal year 1988, \$12,000,000 for fiscal year 1989, \$14,000,000 for fiscal year 1990.

**MISCELLANEOUS PROVISIONS RELATING TO HEALTH
MAINTENANCE ORGANIZATIONS**

MISCELLANEOUS PROVISIONS RELATING TO HEALTH MAINTENANCE ORGANIZATIONS

SECTION 7(b) OF PUBLIC LAW 100-517

SEC. 7. EMPLOYEES' HEALTH BENEFIT PLANS.

(a) * * *

(b) REPEAL OF DUAL CHOICE.—Effective 7 years after the date of the enactment of this Act,¹ section 1310 (42 U.S.C. 300e-9) is amended to read as follows:

“EMPLOYEES’ HEALTH BENEFITS PLANS

“SEC. 1310. (a) In accordance with regulations which the Secretary shall prescribe—

“(1) each employer—

“(A) which is required during any calendar quarter to pay its employees the minimum wage prescribed by section 6 of the Fair Labor Standards Act of 1938 (or would be required to pay its employees such wage but for section 13(a) of such Act), and

“(B) which during such calendar quarter employed an average number of employees of not less than 25, and

“(2) any State and each political subdivision thereof which during any calendar quarter employed an average number of employees of not less than 25, as a condition of payment to the State of funds under section 317, 318, or 1002,

which offers to its employees in the calendar year beginning after such calendar quarter the option of membership in a qualified health maintenance organization which is engaged in the provision of basic health services in a health maintenance organization service area in which at least 25 of such employees reside shall meet the requirements of subsection (b) with respect to any qualified health maintenance organization offered by the employer or State or political subdivision.

“(b)(1) If a health benefits plan offered by an employer or a State or political subdivision includes contributions for services offered under the plan, the employer or State or political subdivision shall make a contribution under the plan for services offered by a qualified health maintenance organization in an amount which does not financially discriminate against an employee who enrolls in such organization. For purposes of the preceding sentence, an employer’s or a State’s or political subdivision’s contribution does not financially discriminate if the employer’s or State’s or political subdivision’s method of determining the contributions on behalf of all employees is reasonable and is designed to assure employees a fair choice among health benefits plans.

¹ Enacted on October 24, 1988.

"(2) Each employer or State or political subdivision which provides payroll deductions as a means of paying employees' contributions for health benefits or which provides a health benefits plan to which an employee contribution is not required shall, with the consent of an employee who exercises option of membership in a qualified health maintenance organization, arrange for the employee's contribution for membership in the organization to be paid through payroll deductions.

"(3) No employer or State or political subdivision shall be required to pay more for health benefits as a result of the application of this subsection than would otherwise be required by any prevailing collective bargaining agreement or other legally enforceable contract for the provision of health benefits between the employer or State or political subdivision and its employees.

"(c) For purposes of this section, the term 'qualified health maintenance organization' means (1) a health maintenance organization which has provided assurances satisfactory to the Secretary that it provides basic and supplemental health services to its members in the manner prescribed by section 1301(b) and that it is organized and operated in the manner prescribed by section 1301(c), and (2) an entity which proposes to become a health maintenance organization and which the Secretary determines will when it becomes operational provide basic and supplemental health services to its members in the manner prescribed by section 1301(b) and will be organized and operated in the manner prescribed by section 1301(c).

"(d)(1) Any employer who knowingly does not comply with one or more of the requirements of paragraph (1) or (2) of subsection (b) shall be subject to a civil penalty of not more than \$10,000. If such noncompliance continues, a civil penalty may be assessed and collected under this subsection for each thirty-day period such noncompliance continues. Such penalty may be assessed by the Secretary and collected in a civil action brought by the United States in a United States district court.

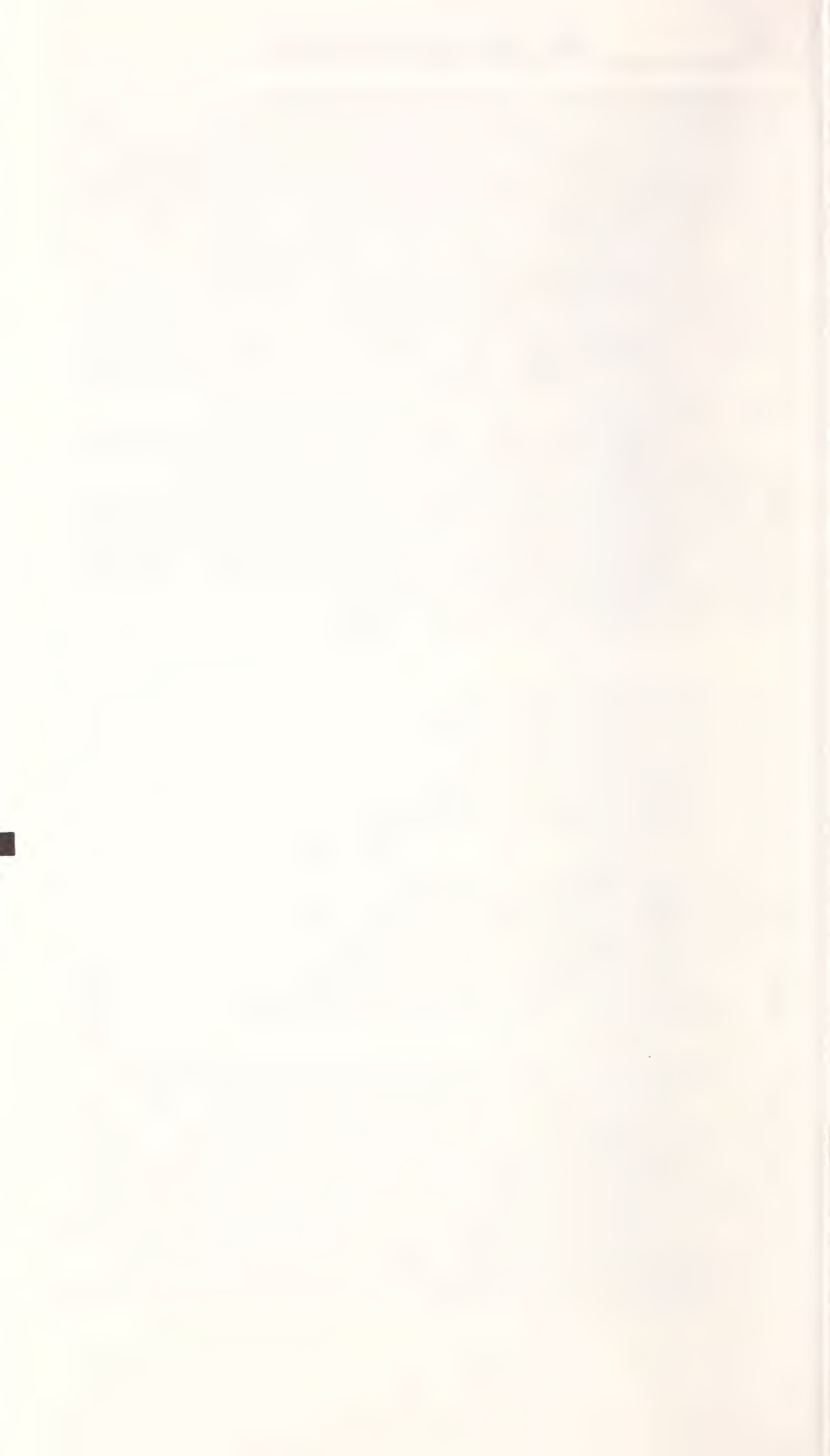
"(2) In any proceeding by the Secretary to assess a civil penalty under this subsection, no penalty shall be assessed until the employer charged shall have been given notice and an opportunity to present its views on such charge. In determining the amount of the penalty, or the amount agreed upon in compromise, the Secretary shall consider the gravity of the noncompliance and the demonstrated good faith of the employer charged in attempting to achieve rapid compliance after notification by the Secretary of a noncompliance.

"(3) In any civil action brought to review the assessment of a civil penalty assessed under this subsection, the court shall, at the request of any party to such action, hold a trial de novo on the assessment of such civil penalty and in any civil action to collect such a civil penalty, the court shall, at the request of any party to such action, hold a trial de novo on the assessment of such civil penalty unless in a prior civil action to review the assessment of such penalty the court held a trial de novo on such assessment.

"(e) For purposes of this section, the term "employer" does not include (1) the Government of the United States, the government of the District of Columbia or any territory or possession of the

United States, a State or any political subdivision thereof, or any agency or instrumentality (including the United States Postal Service and Postal Rate Commission) of any of the foregoing, except that such term includes nonappropriated fund instrumentalities of the Government of the United States; or (2) a church, convention or association of churches, or any organization operated, supervised or controlled by a church, convention or association of churches which organization (A) is an organization described in section 501(c)(3) of the Internal Revenue Code of 1986, and (B) does not discriminate (i) in the employment, compensation, promotion, or termination of employment of any personnel, or (ii) in the extension of staff or other privileges to any physician or other health personnel, because such persons seek to obtain or obtained health care, or participate in providing health care, through a health maintenance organization.

“(f) If the Secretary, after reasonable notice and opportunity for a hearing to a State, finds that it or any of its political subdivisions has failed to comply with paragraph (1) or (2) of subsection (b), the Secretary shall terminate payments to such State under sections 317, 318, and 1002 and notify the Governor of such State that further payments under such sections will not be made to the State until the Secretary is satisfied that there will no longer be any such failure to comply.”.



**MISCELLANEOUS PROVISIONS RELATING TO
OUTCOMES OF HEALTH CARE**

MISCELLANEOUS PROVISIONS RELATING TO OUTCOMES OF HEALTH CARE

SECTION 1142 OF THE SOCIAL SECURITY ACT ¹

RESEARCH ON OUTCOMES OF HEALTH CARE SERVICES AND PROCEDURES

SEC. 1142. (a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—The Secretary, acting through the Administrator for Health Care Policy and Research, shall—

(A) conduct and support research with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically; and

(B) assure that the needs and priorities of the program under title XVIII are appropriately reflected in the development and periodic review and updating (through the process set forth in section 913 of the Public Health Service Act) of treatment-specific or condition-specific practice guidelines for clinical treatments and conditions in forms appropriate for use in clinical practice, for use in educational programs, and for use in reviewing quality and appropriateness of medical care.

(2) EVALUATIONS OF ALTERNATIVE SERVICES AND PROCEDURES.—In carrying out paragraph (1), the Secretary shall conduct or support evaluations of the comparative effects, on health and functional capacity, of alternative services and procedures utilized in preventing, diagnosing, treating, and clinically managing diseases, disorders, and other health conditions.

(3) INITIAL GUIDELINES.—

(A) In carrying out paragraph (1)(B) of this subsection, and section 912(d) of the Public Health Service Act, the Secretary shall, by not later than January 1, 1991, assure the development of an initial set of the guidelines specified in paragraph (1)(B) that shall include not less than 3 clinical treatments or conditions that—

(i)(I) account for a significant portion of expenditures under title XVIII; and

(II) have a significant variation in the frequency or the type of treatment provided; or

(ii) otherwise meet the needs and priorities of the program under title XVIII, as set forth under subsection (b)(3).

¹ 42 U.S.C. 1320b-12.

(B)(i) The Secretary shall provide for the use of guidelines developed under subparagraph (A) to improve the quality, effectiveness, and appropriateness of care provided under title XVIII. The Secretary shall determine the impact of such use on the quality, appropriateness, effectiveness, and cost of medical care provided under such title and shall report to the Congress on such determination by not later than January 1, 1993.

(ii) For the purpose of carrying out clause (i), the Secretary shall expend, from the amounts specified in clause (iii), \$1,000,000 for fiscal year 1990 and \$1,500,000 for each of the fiscal years 1991 and 1992.

(iii) For each fiscal year, for purposes of expenditures required in clause (ii)—

(I) 60 percent of an amount equal to the expenditure involved is appropriated from the Federal Hospital Insurance Trust Fund (established under section 1817); and

(II) 40 percent of an amount equal to the expenditure involved is appropriated from the Federal Supplementary Medical Insurance Trust Fund (established under section 1841).

(b) PRIORITIES.—

(1) IN GENERAL.—The Secretary shall establish priorities with respect to the diseases, disorders, and other health conditions for which research and evaluations are to be conducted or supported under subsection (a). In establishing such priorities, the Secretary shall, with respect to a disease, disorder, or other health condition, consider the extent to which—

(A) improved methods of prevention, diagnosis, treatment, and clinical management can benefit a significant number of individuals;

(B) there is significant variation among physicians in the particular services and procedures utilized in making diagnoses and providing treatments or there is significant variation in the outcomes of health care services or procedures due to different patterns of diagnosis or treatment;

(C) the services and procedures utilized for diagnosis and treatment result in relatively substantial expenditures; and

(D) the data necessary for such evaluations are readily available or can readily be developed.

(2) PRELIMINARY ASSESSMENTS.—For the purpose of establishing priorities under paragraph (1), the Secretary may, with respect to services and procedures utilized in preventing, diagnosing, treating, and clinically managing diseases, disorders, and other health conditions, conduct or support assessments of the extent to which—

(A) rates of utilization vary among similar populations for particular diseases, disorders, and other health conditions;

(B) uncertainties exist on the effect of utilizing a particular service or procedure; or

(C) inappropriate services and procedures are provided.

(3) RELATIONSHIP WITH MEDICARE PROGRAM.—In establishing priorities under paragraph (1) for research and evaluation, and under section 914(a) of the Public Health Service Act for the agenda under such section, the Secretary shall assure that such priorities appropriately reflect the needs and priorities of the program under title XVIII, as set forth by the Administrator of the Health Care Financing Administration.

(c) METHODOLOGIES AND CRITERIA FOR EVALUATIONS.—For the purpose of facilitating research under subsection (a), the Secretary shall—

(1) conduct and support research with respect to the improvement of methodologies and criteria utilized in conducting research with respect to outcomes of health care services and procedures;

(2) conduct and support reviews and evaluations of existing research findings with respect to such treatment or conditions;

(3) conduct and support reviews and evaluations of the existing methodologies that use large data bases in conducting such research and shall develop new research methodologies, including data-based methods of advancing knowledge and methodologies that measure clinical and functional status of patients, with respect to such research;

(4) provide grants and contracts to research centers, and contracts to other entities, to conduct such research on such treatment or conditions, including research on the appropriate use of prescription drugs;

(5) conduct and support research and demonstrations on the use of claims data and data on clinical and functional status of patients in determining the outcomes, effectiveness, and appropriateness of such treatment; and

(6) conduct and support supplementation of existing data bases, including the collection of new information, to enhance data bases for research purposes, and the design and development of new data bases that would be used in outcomes and effectiveness research.

(d) STANDARDS FOR DATA BASES.—In carrying out this section, the Secretary shall develop—

(1) uniform definitions of data to be collected and used in describing a patient's clinical and functional status;

(2) common reporting formats and linkages for such data; and

(3) standards to assure the security, confidentiality, accuracy, and appropriate maintenance of such data.

(e) DISSEMINATION OF RESEARCH FINDINGS AND GUIDELINES.—

(1) IN GENERAL.—The Secretary shall provide for the dissemination of the findings of research and the guidelines described in subsection (a), and for the education of providers and others in the application of such research findings and guidelines.

(2) COOPERATIVE EDUCATIONAL ACTIVITIES.—In disseminating findings and guidelines under paragraph (1), and in provid-

ing for education under such paragraph, the Secretary shall work with professional associations, medical specialty and subspecialty organizations, and other relevant groups to identify and implement effective means to educate physicians, other providers, consumers, and others in using such findings and guidelines, including training for physician managers within provider organizations.

(f) **EVALUATIONS.**—The Secretary shall conduct and support evaluations of the activities carried out under this section to determine the extent to which such activities have had an effect on the practices of physicians in providing medical treatment, the delivery of health care, and the outcomes of health care services and procedures.

(g) **RESEARCH WITH RESPECT TO DISSEMINATION.**—The Secretary may conduct or support research with respect to improving methods of disseminating information on the effectiveness and appropriateness of health care services and procedures.

(h) **REPORT TO CONGRESS.**—Not later than February 1 of each of the years 1991 and 1992, and of each second year thereafter, the Secretary shall report to the Congress on the progress of the activities under this section during the preceding fiscal year (or preceding 2 fiscal years, as appropriate), including the impact of such activities on medical care (particularly medical care for individuals receiving benefits under title XVIII).

(i) **AUTHORIZATION OF APPROPRIATIONS.**—

(1) **IN GENERAL.**—There are authorized to be appropriated to carry out this section—

- (A) \$50,000,000 for fiscal year 1990;
- (B) \$75,000,000 for fiscal year 1991;
- (C) \$110,000,000 for fiscal year 1992;
- (D) \$148,000,000 for fiscal year 1993; and
- (E) \$185,000,000 for fiscal year 1994.

(2) **SPECIFICATIONS.**—For the purpose of carrying out this section, for each of the fiscal years 1990 through 1992 an amount equal to two-thirds of the amounts authorized to be appropriated under paragraph (1), and for each of the fiscal years 1993 and 1994 an amount equal to 70 percent of such amounts, are to be appropriated in the following proportions from the following trust funds:

(A) 60 percent from the Federal Hospital Insurance Trust Fund (established under section 1817).

(B) 40 percent from the Federal Supplementary Medical Insurance Trust Fund (established under section 1841).

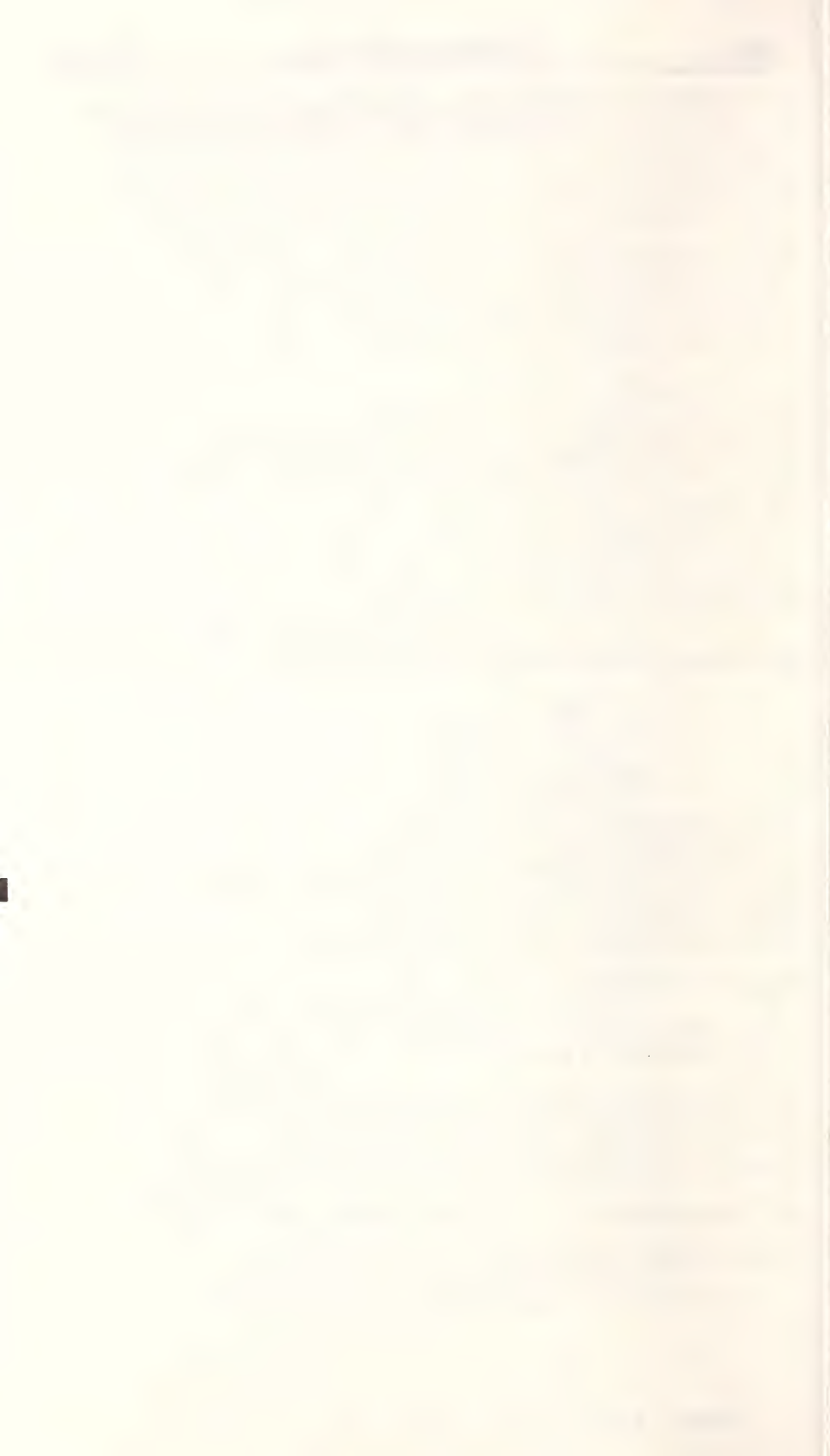
(3) **ALLOCATIONS.**—

(A) For each fiscal year, of the amounts transferred or otherwise appropriated to carry out this section, the Secretary shall reserve appropriate amounts for each of the purposes specified in clauses (i) through (iv) of subparagraph (B).

(B) The purposes referred to in subparagraph (A) are—

- (i) the development of guidelines, standards, performance measures, and review criteria;
- (ii) research and evaluation;

- (iii) data-base standards and development; and
- (iv) education and information dissemination.



**MISCELLANEOUS PROVISIONS RELATING TO WAIVER
REGARDING TITLE VI OF PUBLIC HEALTH SERVICE ACT**

MISCELLANEOUS PROVISIONS RELATING TO WAIVER REGARDING TITLE VI OF PUBLIC HEALTH SERVICE ACT

SUBTITLE D OF TITLE VII OF PUBLIC LAW 100-607

Subtitle D—Waiver of Liability for Certain Sale of Facility Under Program of Con- struction and Modernization of Medical Facilities

SEC. 731. ESTABLISHMENT OF WAIVER AUTHORITY.

(a) IN GENERAL.—If, pursuant to subsection (b) of section 732, the Secretary of Health and Human Services makes a certification of compliance with the conditions described in subsection (a) of such section, section 609 of the Public Health Service Act (42 U.S.C. 291i) shall not, with respect to the transferor and transferee described in subsection (b), apply to the sale on November 26, 1986, of the medical facility—

(1) located in Blanding, in the State of Utah;

(2) known, prior to such date, as San Juan County Nursing Home; and

(3) with respect to which funds were received during the years 1967 through 1970 pursuant to title VI of the Public Health Service Act (42 U.S.C. 291 et seq.).

(b) DESCRIPTION OF PARTIES TO SALE.—In the sale described in subsection (a), the transferor is San Juan County, a political subdivision of the State of Utah, and the transferee is Auburn Manor Holding Corporation, a corporation under the laws of the State of California.

SEC. 732. CONDITIONS OF WAIVER.

(a) IN GENERAL.—The conditions referred to in section 731(a) are that, not later than the expiration of the 12-month period beginning on the date of the enactment of this Act¹—

(1)(A) San Juan County establish an irrevocable trust with a res of \$321,057 for the sole purpose of satisfying, with respect to the medical facility described in section 731(a), the obligation of San Juan County under regulations issued under clause (2) of section 603(e) of the Public Health Service Act (42 U.S.C. 291c(e));

(B) except to the extent inconsistent with this title², San Juan³ establish such trust in accordance with regulations is-

¹ Enacted November 4, 1988.

² So in original. Probably should be "subtitle".

³ So in original. Probably should be "San Juan County". See section 734(2).

sued under section 609(d)(1)(A) of such Act for trusts established pursuant to such section; and

(C) San Juan County agree—

(i) except to the extent inconsistent with this title¹, to administer such trust in accordance with regulations issued under such section 609(d)(1)(A) of such Act; and

(ii) with respect to the obligation described in subparagraph (A)—

(I) to carry out such obligation at the medical facility known as San Juan County Hospital and located in Monticello, in the State of Utah;

(II) to ensure that uncompensated services provided at any location other than such medical facility will not be reimbursed from the trust established pursuant to subparagraph (A); and

(III) not to seek contribution from Auburn Corporation toward the satisfaction of such obligation; and

(2) Auburn Corporation agree—

(A) to satisfy, with respect to the medical facility described in section 731(a), the obligation of San Juan County under regulations issued under clause (1) of section 603(e) of the Public Health Service Act;

(B) to satisfy such obligation at the medical facility described in section 731(a); and

(C) not to seek contribution from San Juan County toward the satisfaction of such obligation.

(b) DETERMINATION AND CERTIFICATION OF SATISFACTION OF CONDITIONS.—The Secretary shall make a determination of whether the conditions described in subsection (a) are satisfied by San Juan County and Auburn Corporation within the period described in such subsection. If the Secretary makes a determination that the conditions have been satisfied, the Secretary shall certify to the Congress the fact of such determination.

SEC. 733. MONITORING OF COMPLIANCE WITH AGREEMENTS AND EFFECT OF FAILURE TO COMPLY.

(a) MONITORING.—The Secretary shall determine the extent to which San Juan County and Auburn Corporation are carrying out their respective duties under the agreements made pursuant to the conditions described in section 732(a).

(b) FAILURE TO COMPLY.—

(1) If the conditions described in section 732(a) are not satisfied by San Juan County and Auburn Corporation within the period described in such section, the Secretary shall ensure that proceedings under section 609 of the Public Health Service Act (42 U.S.C. 291i) with respect to the sale described in section 731(a) are commenced or continued against San Juan County or Auburn Corporation, or both, as determined by the Secretary.

(2) If San Juan County or Auburn Corporation fails to carry out its duties under the agreements made pursuant to the conditions described in section 732(a), the Secretary shall

¹ So in original. Probably should be "subtitle".

ensure that proceedings described in paragraph (1) are commenced or continued against San Juan County or Auburn Corporation, respectively.

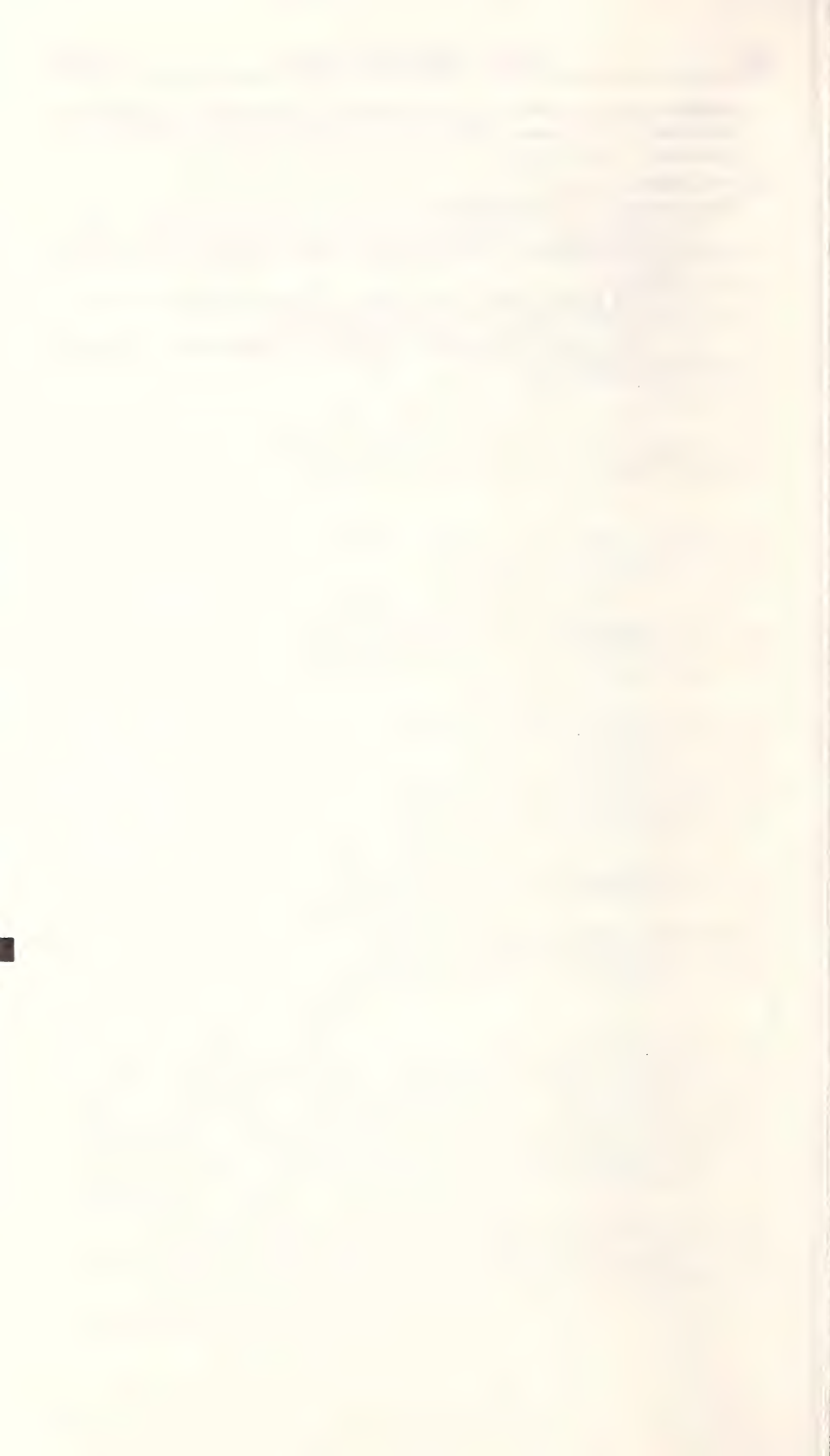
SEC. 734. DEFINITIONS.

For purposes of this subtitle:

(1) The term "Auburn Corporation" means Auburn Manor Holding Corporation, a corporation under the laws of the State of California.

(2) The term "San Juan County" means San Juan County, a political subdivision of the State of Utah.

(3) The term "Secretary" means the Secretary of Health and Human Services.



**MISCELLANEOUS PROVISIONS RELATING TO CON-
STRUCTION OF CERTAIN BIOMEDICAL RESEARCH
FACILITIES**



MISCELLANEOUS PROVISIONS RELATING TO CONSTRUCTION OF CERTAIN BIOMEDICAL RESEARCH FACILITIES

PUBLIC LAW 101-190¹

SECTION 1. AUTHORITY FOR GRANT FOR CONSTRUCTION OF BIOMEDICAL RESEARCH FACILITIES.

(a) IN GENERAL.—Of the aggregate amounts appropriated for fiscal years 1990 and 1991 to carry out the purposes of title IV of the Public Health Service Act through the National Institutes of Health, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, may reserve not more than \$25,000,000 for making a grant to a public or nonprofit private entity for constructing facilities for the purpose of the development and breeding of specialized strains of mice (including inbred and mutant mice) for use in biomedical research.

(b) COMPETITIVE AWARD PROCESS.—The grant under subsection (a) may be awarded only on a competitive basis after review in accordance with section 4(a).

SEC. 2. TWENTY-YEAR OBLIGATION WITH RESPECT TO BREEDING OF SPECIALIZED MICE FOR BIOMEDICAL RESEARCH.

(a) IN GENERAL.—The Secretary may not make a grant under section 1 unless, subject to subsection (b), the applicant for the contract² agrees that—

(1) throughout the 20-year period beginning 90-days after the date of the completion of the construction of facilities pursuant to the grant, the facilities will be utilized only for the purpose described in section 1(a);

(2) during such period, the applicant will, to the extent practicable, develop and breed such mice in numbers sufficient to assist in meeting the need for such mice in biomedical research conducted or supported by the Secretary; and

(3) during such period, the applicant will, upon the request of the Secretary, sell such mice to the Secretary for purposes of such research at a price reasonably related to the cost of the production of the mice.

(b) TRANSFER OF OBLIGATION.—

(1) IN GENERAL.—With respect to the obligation under subsection (a), the grantee under section 1 (and any transferee or purchaser under this subsection) may—

(A) transfer the obligation to a public or nonprofit private entity if the proposed transferee has entered into an agreement with the Secretary to assume the obligation; and

¹ Public Law 101-190 is codified at 42 U.S.C. 289e note. The Public Law was amended by section 4(a) of Public Law 101-374.

² So in original. Probably should be "grant".

(B) convey its interest in the facilities involved if the proposed purchaser of the interest is a public or nonprofit entity that has entered into an agreement with the Secretary to assume the obligation.

(2) TRANSFER PRIOR TO COMPLETION OF CONSTRUCTION.—If, for purposes of paragraph (1), a transfer or conveyance is proposed to be made before the completion of the construction of facilities pursuant to section 1, the Secretary may not authorize the transfer or conveyance unless the agreement involved provides that the transferee or purchaser will assume all remaining responsibilities under any agreements made pursuant to this Act by the grantee under such section and the Federal Government.

(3) TERMINATION OF OBLIGATION.—If, for purposes of paragraphs (1) and (2), a transfer or conveyance is made in accordance with such paragraphs, the obligation pursuant to subsection (a), and all other responsibilities pursuant to this Act, of the transferor involved shall terminate.

(c) REQUIREMENT OF STATUS AS PUBLIC OR NONPROFIT PRIVATE ENTITY.—The Secretary may not enter into any agreement under subsection (a) or (b) unless the agreement provides that the obligation involved includes the requirement that the obligation may be satisfied only by a public or nonprofit private entity.

(d) ASSURANCES OF SUFFICIENT FINANCIAL RESOURCES.—

(1) ORIGINAL CONTRACTOR¹.—The Secretary may not make a grant under section 1 unless the applicant for the contract provides assurances satisfactory to the Secretary that, throughout the 20-year period described in subsection (a), the applicant will have access to financial resources sufficient to comply with the agreement under such subsection.

(2) TRANSFEREES AND PURCHASERS.—The Secretary may not approve a transfer or conveyance under subsection (b) unless the transferee or purchaser provides assurances satisfactory to the Secretary that, throughout the remaining portion of the 20-year period described in subsection (a), the transferee or purchaser will have access to financial resources sufficient to comply with its obligation pursuant to such subsection.

SEC. 3. REQUIREMENT OF MATCHING FUNDS.

(a) IN GENERAL.—The Secretary may not make a grant under section 1 unless the applicant for the contract² agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such section, to make available (directly or through donations from public or private entities) contributions toward such costs in an amount equal to \$1 for each \$3 of Federal funds provided pursuant to the contract² under section 1.

(b) DETERMINATION OF AMOUNT OF CONTRIBUTION.—Contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including existing plant and equipment or services

¹ Section 4(a) of Public Law 101-374 evinced the clear intent to strike the word "contractor" and insert "grantee", but the amendatory instructions cannot be executed because the instruction used the incorrect typeface.

² Section 4(a) of Public Law 101-374 provided that section 3(a) is amended by striking "the contract" and inserting "the grant". The amendment cannot be executed because the amendment does not specify which of the two instances of such term is the subject of the amendment.

throughout the 20-year period described in section 2(a)(1) (and including such specialized strains of mice as the Secretary may request for purposes of biomedical research). Amounts provided by any agency of the Federal Government other than the Department of Health and Human Services, and services assisted or subsidized by any such agency, shall be included in the amount of such contributions.

SEC. 4. ADDITIONAL REQUIREMENTS.

(a) SUBMISSION AND APPROVAL OF CONSTRUCTION PLAN.—

(1) IN GENERAL.—The Secretary may not make a grant under section 1 unless the applicant for the grant submits to the Secretary a plan for the construction of facilities pursuant to such section and unless the Secretary approves the plan. The Secretary may not approve such a plan unless the plan has been recommended for approval by the panel convened under paragraph (2)(A).

(2) EXPERT PANEL FOR ADVISING SECRETARY WITH RESPECT TO PLAN.—

(A) The Secretary shall convene a panel of appropriately qualified individuals for the purpose of providing architectural, financial, and scientific advice to the Secretary regarding appropriate standards and specifications for the construction, financing, and use of facilities pursuant to section 1. The panel may not approve a plan submitted under paragraph (1) unless the panel determines that amounts provided under section 1 will not, during the twenty-year period described in section 2(a), be expended to increase significantly, relative to April 1989, the sale of mice other than mutant and inbred strains of mice necessary for the conduct of biomedical research.

(B) Members of the panel convened under paragraph (1) who are officers or employees of the United States may not receive compensation for service on the panel in addition to the compensation otherwise received for duties carried out as such officers or employees. Other members of such panel shall receive compensation for each day (including traveltime) engaged in carrying out the duties of the panel. Such compensation may not be in an amount in excess of the maximum rate of basic pay payable for GS-18 of the General Schedule.

(b) SITE OF CONSTRUCTION.—The Secretary may not make a grant under section 1 unless—

(1) the applicant for the grant provides to the Secretary a description of the site for the construction of facilities pursuant to such section; and

(2) the Secretary determines that title to the site is vested in the applicant or that the applicant has a sufficient possessory interest in such site for the twenty-year period described in section 2(a).

(c) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under section 1 unless—

(1) an application for the grant is submitted to the Secretary;

(2) the application contains the agreements required in this Act and provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this Act.

SEC. 5. FAILURE TO COMPLY WITH AGREEMENTS.

(a) REPAYMENT OF PAYMENTS.—

(1) IN GENERAL.—The Secretary may, subject to subsection (c), require the grantee under section 1 to repay any payments received under such section by the grantee that the Secretary determines were not expended by the grantee in accordance with the agreements required to be contained in the application submitted by the grantee pursuant to section 4(c).

(2) OFFSET AGAINST CURRENT PAYMENTS.—If a grantee under section 1 fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against the amount of any payment due to be paid under such section to the grantee.

(b) WITHHOLDING OF PAYMENTS.—

(1) IN GENERAL.—The Secretary may, subject to subsection (c), withhold payments due under section 1 if the Secretary determines that the grantee under such section is not expending payments received under such section in accordance with the agreements required to be contained in the application submitted by the grantee pursuant to section 4(c).

(2) TERMINATION OF WITHHOLDING.—The Secretary shall cease withholding payments under paragraph (1) if the Secretary determines that there are reasonable assurances that the grantee under section 1 will expend amounts received under such section in accordance with the agreements referred to in such paragraph.

(3) EFFECT OF MINOR NONCOMPLIANCE.—The Secretary may not withhold funds under paragraph (1) from the grantee under section 1 for a minor failure to comply with the agreements referred to in such paragraph.

(c) OPPORTUNITY FOR HEARING.—Before requiring repayment of payments under subsection (a)(1), or withholding payments under subsection (b)(1), the Secretary shall provide to the grantee under section 1 an opportunity for a hearing conducted within the State in which facilities are constructed pursuant to such section.

SEC. 6. RECOVERY PROCEEDINGS FOR VIOLATION OF REQUIREMENT WITH RESPECT TO MINIMUM PERIOD OF BREEDING OF SPECIALIZED MICE.

(a) RIGHT OF RECOVERY.—If the grantee under section 1, or any transferee or purchaser under section 2, violates its obligation under such section (including any violation under subsection (c) of such section), the United States shall be entitled to recover an amount equal to the sum of—

(1) an amount determined in accordance with paragraph (1)(A) of subsection (b); and

(2) an amount determined in accordance with paragraph (2)(A) of such subsection.

(b) DETERMINATION OF AMOUNTS.—

(1) FEDERAL PERCENTAGE OF FAIR MARKET VALUE.—

(A) The amount referred to in paragraph (1) of subsection (a) is the product of—

(i) an amount equal to the fair market value, during the period in which recovery is sought under subsection (a), of the facilities constructed pursuant to section 1, as determined in accordance with subparagraph (B); and

(ii) a percentage equal to the quotient of—

(I) the total amounts provided by the Federal Government for the construction of such facilities; divided by

(II) the total costs of the construction of such facilities.

(B) For purposes of subparagraph (A)(i), fair market value shall be determined through—

(i) an agreement entered into by the United States and the entity from whom the United States is seeking recovery under subsection (a); or

(ii) an action brought in the district court of the United States for the district in which the facilities involved are located.

(2) INTEREST.—

(A) The amount referred to in paragraph (2) of subsection (a) is an amount representing interest on the amount determined under paragraph (1). Such interest shall accrue during the period described in subparagraph (B) and shall accrue at a rate determined by the Secretary on the basis of the average of the bond equivalent of the weekly 90-day Treasury bill auction rate.

(B) The period referred to in subparagraph (A) is the period—

(i) beginning on the date of the violation of the obligation under section 2, or if the entity involved provides notice to the Secretary of the violation not later than 10 days after the date of the violation, beginning on the expiration of the 180-day period beginning on the date that the notice is received by the Secretary; and

(ii) ending on the date on which the United States collects the amount determined under paragraph (1).

(c) WAIVER OF RECOVERY RIGHTS.—The Secretary may waive, in whole or in part, the right of the United States to recover amounts under this section for good cause shown, as determined by the Secretary.

(d) CLARIFICATION WITH RESPECT TO LIEN ON FACILITIES.—The right of recovery of the United States under subsection (a) shall not constitute a lien on the facilities involved with respect to which such recovery is sought.

SEC. 7.¹ DEFINITION.

For purposes of this Act, the term "Secretary" means the Secretary of Health and Human Services.

¹Public Law 101-190 contains a section 8. The section does not appear in this compilation because the section was amendatory in nature.

**MISCELLANEOUS PROVISIONS RELATING TO AGING
RESEARCH**



MISCELLANEOUS PROVISIONS RELATING TO AGING RESEARCH

TITLE III OF PUBLIC LAW 101-557

(References in brackets [] are to title 42, United States Code)

TITLE III—TASK FORCE ON AGING RESEARCH

SEC. 301. [242q] ESTABLISHMENT AND DUTIES.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish a Task Force on Aging Research.

(b) DUTIES.—With respect to aging research (as defined in section 305), the Task Force each fiscal year shall—

(1) make recommendations to the Secretary specifying the particular projects of research, or the particular categories of research, that should be conducted or supported by the Secretary;

(2) of the projects specified under paragraph (1), make recommendations to the Secretary of the projects that should be given priority in the provision of funds; and

(3) make recommendations to the Secretary of the amount of funds that should be appropriated for such research.

(c) PROVISION OF INFORMATION TO THE PUBLIC.—The Task Force may make available to health professionals, and to other members of the public, information regarding the research described in subsection (b).

SEC. 302. [242q-1] MEMBERSHIP.

(a) COMPOSITION.—The Task Force shall be composed of—

(1) the Assistant Secretary for Health;

(2) the Surgeon General of the Public Health Service;

(3) the Assistant Secretary for Planning and Evaluation;

(4) the Director of the National Institute on Aging, and the Directors of such other agencies of the National Institutes of Health as the Secretary determines to be appropriate;

(5) the Commissioner of the Administration on Aging;

(6) the Commissioner of Food and Drugs;

(7) the Chief Medical Director of the Department of Veterans Affairs;¹

(8) the Administrator of the the Alcohol, Drug Abuse, and Mental Health Administration;²

¹ See footnote 1 on page 299.

² Now the Substance Abuse and Mental Health Services Administration.

(9) the Administrator of the Health Care Financing Administration;

(10) the Commissioner of Social Security;

(11) the Administrator for Health Care Policy and Research;

(12) two Members of the House of Representatives appointed by the Speaker of the House in consultation with the Minority Leader, and two members of the Senate appointed by the Majority Leader in consultation with the Minority Leader, not more than one of whom from each body shall be members of the same political party; and

(13) three members of the general public, to be appointed by the Secretary, that shall include one representative each from—

(A) a nonprofit group representing older Americans;

(B) a private voluntary health organization concerned with the health problems affecting older Americans; and

(C) a nonprofit organization concerned with research related to the health and independence of older Americans.

(b) CHAIR.—The Secretary, acting through either the Assistant Secretary for Health or the Director of the National Institute on Aging, shall serve as the Chair of the Task Force.

(c) QUORUM.—A majority of the members of the Task Force shall constitute a quorum, and a lesser number may hold hearings.

(d) MEETINGS.—The Task Force shall meet periodically at the call of the Chair, but in no event less than twice each year.

(e) COMPENSATION AND EXPENSES.—

(1) COMPENSATION.—Members of the Task Force who are not regular full-time employees of the United States Government shall, while attending meetings and conferences of the Task Force or otherwise engaged in the business of the Task Force (including traveltime), be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding the rate specified at the time of such service under GS-18 of the General Schedules established under section 5332 of title 5, United States Code.

(2) EXPENSES.—While away from their homes or regular places of business on the business of the Task Force, members of such Task Force may be allowed travel expenses, including per diem in lieu of subsistence, as is authorized under section 5703 of title 5, United States Code, for persons employed intermittently in the Government service.

SEC. 303. [242q-2] ADMINISTRATIVE STAFF AND SUPPORT.

The Secretary, acting through either the Assistant Secretary for Health or the Director of the National Institute on Aging, shall appoint an Executive Secretary for the Task Force and shall provide the Task Force with such administrative staff and support as may be necessary to enable the Task Force to carry out subsections (b) and (c) of section 301.

SEC. 304. [242q-3] REPORTS.

(a) **IN GENERAL.**—Not later than 1 year after the date of the enactment of this Act¹, and annually thereafter, the Task Force shall prepare and submit to the Secretary, and to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report providing the recommendations required in section 301(b).

(b) **AVAILABILITY TO PUBLIC.**—The Task Force may make available to the public copies of the reports required in subsection (a).

SEC. 305. [242q-4] DEFINITIONS.

For purposes of this title:

(1) **AGING RESEARCH.**—

(A) The term “aging research” means research on the aging process and on the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause. Such research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals.

(B) For purposes of subparagraph (A), the term “independence”, with respect to diseases, disorders, and complications of aging, means the functional ability of individuals to perform activities of daily living or instrumental activities of daily living without assistance or supervision.

(2) **SECRETARY.**—The term “Secretary” means the Secretary of Health and Human Services.

(3) **TASK FORCE.**—The term “Task Force” means the Task Force on Aging Research established under section 301(a).

SEC. 306. [242q-5] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this title, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1993.

¹ Enacted November 15, 1990.



**MISCELLANEOUS PROVISIONS RELATING TO
CONSTRUCTION OF CERTAIN MEDICAL FACILITY**

MISCELLANEOUS PROVISIONS RELATING TO CONSTRUCTION OF CERTAIN MEDICAL FACILITY

SECTION 6 OF PUBLIC LAW 101-590

SEC. 6. GRANT REGARDING MEDICAL FACILITIES.

(a) IN GENERAL.—The Secretary of Health and Human Services may make a grant to the George Washington University Hospital, a nonprofit private hospital located in the District of Columbia, for the purpose of constructing or modernizing a medical facility of such Hospital.

(b) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees, with respect to the costs of carrying out the purpose described in such subsection, to make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount that is not less than \$1 for each \$1 of Federal funds provided in the grant.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—In determining the amount of non-Federal contributions in cash that has been provided for purposes of paragraph (1), the Secretary may not include any amounts provided by the Federal Government.

(c) OBLIGATIONS REGARDING FREE CARE AND COMMUNITY SERVICE.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that clauses (i) and (ii) of section 1621(b)(1)(K) of the Public Health Service Act (and regulations issued under such clauses), and section 1622 of such Act (and regulations issued under such section), will apply with respect to the medical facility constructed or modernized with the grant to the same extent and in the same manner as such sections and regulations apply with respect to medical facilities constructed or modernized with funds that have been paid under title XVI of such Act.

(d) DEFINITION.—For purposes of this Act¹, the term "Secretary" means the Secretary of Health and Human Services.

(e) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—

(A) Subject to subparagraph (B), there is authorized to be appropriated an aggregate \$50,000,000 for the fiscal years 1992 through 1995².

(B) The authorization of appropriations established in subparagraph (A) is effective only with respect to appropriations made from allocations under section 302(b) of the Congressional Budget Act of 1974—

¹ So in original. Probably should be "section".

² So in original. The provision probably should specify the purpose for which the authorization of appropriations is provided.

(i) for the Subcommittee on the District of Columbia of the Committee on Appropriations of the House of Representatives, in the case of any bill, resolution, or amendment considered in the House; and

(ii) for the Subcommittee on District of Columbia of the Committee on Appropriations of the Senate, in the case of any bill, resolution, or amendment considered in the Senate.

(2) AMOUNT OF GRANT.—Subject to the extent of amounts made available in appropriations Act, the amount of a grant under subsection (a) shall be \$50,000,000.

**MISCELLANEOUS PROVISIONS RELATING TO FETAL
TISSUE TRANSPLANTATION RESEARCH**

MISCELLANEOUS PROVISIONS RELATING TO FETAL TISSUE TRANSPLANTATION RESEARCH

SECTION 113 OF PUBLIC LAW 103-43¹

SEC. 113. NULLIFICATION OF MORATORIUM.

(a) IN GENERAL.—Except as provided in subsection (c), no official of the executive branch may impose a policy that the Department of Health and Human Services is prohibited from conducting or supporting any research on the transplantation of human fetal tissue for therapeutic purposes. Such research shall be carried out in accordance with section 498A of the Public Health Service Act (as added by section 111 of this Act), without regard to any such policy that may have been in effect prior to the date of the enactment of this Act.

(b) PROHIBITION AGAINST WITHHOLDING OF FUNDS IN CASES OF TECHNICAL AND SCIENTIFIC MERIT.—

(1) IN GENERAL.—Subject to subsection (b)(2) of section 492A of the Public Health Service Act (as added by section 101 of this Act), in the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may not withhold funds for the research if—

(A) the research has been approved for purposes of subsection (a) of such section 492A;

(B) the research will be carried out in accordance with section 498A of such Act (as added by section 111 of this Act); and

(C) there are reasonable assurances that the research will not utilize any human fetal tissue that has been obtained in violation of section 498B(a) of such Act (as added by section 112 of this Act).

(2) STANDING APPROVAL REGARDING ETHICAL STATUS.—In the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the issuance in December 1988 of the Report of the Human Fetal Tissue Transplantation Research Panel shall be deemed to be a report—

(A) issued by an ethics advisory board pursuant to section 492A(b)(5)(B)(ii) of the Public Health Service Act (as added by section 101 of this Act); and

(B) finding, on a basis that is neither arbitrary nor capricious, that the nature of the research is such that it is not unethical to conduct or support the research.

(c) AUTHORITY FOR WITHHOLDING FUNDS FROM RESEARCH.—In the case of any research on the transplantation of human fetal tis-

¹42 U.S.C. 289g-1 note.

sue for therapeutic purposes, the Secretary of Health and Human Services may withhold funds for the research if any of the conditions specified in any of subparagraphs (A) through (C) of subsection (b)(1) are not met with respect to the research.

(d) DEFINITION.—For purposes of this section, the term “human fetal tissue” has the meaning given such term in section 498A(f) of the Public Health Service Act (as added by section 111 of this Act).

CERTAIN REORGANIZATION PLANS



REORGANIZATION PLAN NO. 1 OF 1953

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SECTION 1. *Creation of Department; Secretary.*—There is hereby established an executive department, which shall be known as the Department of Health, Education, and Welfare (hereafter in this reorganization plan referred to as the Department). There shall be at the head of the Department a Secretary of Health, Education, and Welfare (hereafter in this reorganization plan referred to as the Secretary), who shall be appointed by the President by and with the advice and consent of the Senate, and who shall receive compensation at the rate now or hereafter prescribed by law for the heads of executive departments. The Department shall be administered under the supervision and direction of the Secretary.

SEC. 2. *Under Secretary and Assistant Secretaries.*—There shall be in the Department an Under Secretary of Health, Education, and Welfare and five¹ Assistant Secretaries of Health, Education, and Welfare, each of whom shall be appointed by the President by and with the advice and consent of the Senate, shall perform such functions as the Secretary may prescribe, and shall receive compensation at the rate now or hereafter provided by law for under secretaries and assistant secretaries, respectively, of executive departments. The Under Secretary (or, during the absence or disability of the Under Secretary or in the event of a vacancy in the office of Under Secretary, an Assistant Secretary determined according to such order as the Secretary shall prescribe) shall act as Secretary during the absence or disability of the Secretary or in the event of a vacancy in the office of Secretary.

SEC. 4.² *Commissioner of Social Security.*—There shall be in the Department a Commissioner of Social Security who shall be appointed by the President by and with the advice and consent of the Senate, shall perform such functions concerning social security and public welfare as the Secretary may prescribe, and shall receive compensation at the rate now or hereafter fixed by law for grade GS-18 of the general schedule established by the Classification Act of 1949, as amended.

SEC. 5. *Transfers to the Department.*—All functions of the Federal Security Administrator are hereby transferred to the Secretary. All agencies of the Federal Security Agency, together with their respective functions, personnel, property, records, and unexpended balances of appropriations, allocations, and other funds (available or to be made available), and all other functions, personnel, property, records, and unexpended balances of appropriations, allocations, and other funds (available or to be made available) of

¹ Section 1(b) of Public Law 89-234 provided for an additional Assistant Secretary.

² Section 3 was repealed by section 4 of Public Law 89-115.

the Federal Security Agency are hereby transferred to the Department.

SEC. 6. *Performance of functions of the Secretary.*—The Secretary may from time to time make such provisions as the Secretary deems appropriate authorizing the performance of any of the functions of the Secretary by any other officer, or by any agency or employee, of the Department.

SEC. 7. *Administrative services.*—In the interest of economy and efficiency the Secretary may from time to time establish central administrative services in the fields of procurement, budgeting, accounting, personnel, library, legal, and other services and activities common to the several agencies of the Department; and the Secretary may effect such transfers within the Department of the personnel employed, the property and records used or held, and the funds available for use in connection with such administrative-service activities as the Secretary may deem necessary for the conduct of any services so established: *Provided*, That no professional or substantive functions vested by law in any officer shall be removed from the jurisdiction of such officer under this section.

SEC. 8. *Abolitions.*—The Federal Security Agency (exclusive of the agencies thereof transferred by sec. 5 of this reorganization plan), the offices of Federal Security Administrator and Assistant Federal Security Administrator created by Reorganization Plan No. 1 (53 Stat. 1423), the two offices of assistant heads of the Federal Security Agency created by Reorganization Plan No. 2 of 1946 (60 Stat. 1095), and the office of Commissioner for Social Security created by section 701 of the Social Security Act, as amended (64 Stat. 558), are hereby abolished. The Secretary shall make such provisions as may be necessary in order to wind up any outstanding affairs of the Agency and the offices abolished by this section which are not otherwise provided for in this reorganization plan.

SEC. 9. *Interim provisions.*—The President may authorize the persons who immediately prior to the time this reorganization plan takes effect occupy the offices of Federal Security Administration, Assistant Security Administrator, assistant heads of the Federal Security Agency, the Commissioner for Social Security to act as Secretary, Under Secretary, and Assistant Secretaries of Health, Education, and Welfare and as Commissioner of Social Security, respectively, until those offices are filled by appointment in the manner provided by sections 1, 2, and 4 of this reorganization plan, but not for a period of more than 60 days. While so acting, such persons shall receive compensation at the rates provided by this reorganization plan for the offices the functions of which they perform.

REORGANIZATION PLAN NO. 3 OF 1966

PUBLIC HEALTH SERVICE

SECTION 1. *Transfer of functions.*—(a) Except as otherwise provided in subsection (b) of this section, there are hereby transferred to the Secretary of Health, Education, and Welfare (hereinafter referred to as the Secretary) all functions of the Public Health Service, of the Surgeon General of the Public Health Service, and of all

other officers and employees of the Public Health Service, and all functions of all agencies of or in the Public Health Service.

(b) This section shall not apply to the functions vested by law in any advisory council, board, or committee of or in the Public Health Service which is established by law or is required by law to be established.

SEC. 2. *Performances of transferred functions.*—The Secretary may from time to time make such provisions as he shall deem appropriate authorizing the performance of any of the functions transferred to him by the provisions of this reorganization plan by any officer, employee, or agency of the Public Health Service or of the Department of Health, Education, and Welfare.

SEC. 3. *Abolitions.*—(a) The following agencies of the Public Health Service are hereby abolished:

(1) The Bureau of Medical Services, including the office of Chief of the Bureau of Medical Services.

(2) The Bureau of State Services, including the office of Chief of the Bureau of State Services.

(3) The agency designated as the National Institutes of Health (42 U.S.C. 203), including the office of Director of the National Institutes of Health (42 U.S.C. 206(b)) but excluding the several research Institutes in the agency designated as the National Institutes of Health.

(4) The agency designated as the Office of the Surgeon General (42 U.S.C. 203(1)), together with the office held by the Deputy Surgeon General (42 U.S.C. 206(a)).

(b) The Secretary shall make such provisions as he shall deem necessary respecting the winding up of any outstanding affairs of the agencies abolished by the provisions of this section.

SEC. 4. *Incidental transfers.*—As he may deem necessary in order to carry out the provisions of this reorganization plan, the Secretary may from time to time effect transfers within the Department of Health, Education, and Welfare of any of the records, property, personnel and unexpected balances (available or to be made available) of appropriations, allocations, and other funds of the Department which relate to functions affected by this reorganization plan.



TABLES



MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION

Title	Public law	Purpose of the Act
1. National Mental Health Act	Public Law 79-487, July 3, 1946 (60 Stat. 421), H.R. 4512, H. Rept. 1445, S. Rept. 1353.	To amend the PHS Act to provide for research relating to psychiatric disorders and to aid in the development of more effective methods of prevention, diagnosis, and treatment of such disorders, and for other purposes.
2. Hospital Survey and Construction Act.	Public Law 79-725, Aug. 13, 1946 (60 Stat. 1040), S. 191, S. Rept. 674, H. Rept. 2519.	To amend the PHS Act to authorize grants to the States for surveying their hospitals and public health centers and for planning construction of additional facilities, and to authorize grants to assist in such construction.
3. National Heart Act	Public Law 80-655, June 16, 1948 (62 Stat. 464), S. 2215, S. Rept. 1298, H. Rept. 2144.	To amend the PHS Act to support research and training in diseases of the heart and circulation, and to aid the States in the development of community programs for the control of these diseases, and for other purposes.
4. National Dental Research Act	Public Law 80-755, June 24, 1948 (62 Stat. 598), H.R. 6726 (S. 176), H. Rept. 2158.	To amend the PHS Act to provide for, foster, and aid in coordinating research relating to dental diseases and conditions, and for other purposes.
5. Hospital Survey and Construction Amendments of 1949.	Public Law 81-380, Oct. 25, 1949 (63 Stat. 898), S. 614 (H.R. 5903), S. Rept. 790.	To amend the Hospital Survey and Construction Act (title VI of the PHS Act), to extend its duration and provide greater financial assistance in the construction of hospitals, and for other purposes.
6. (No authorized title—Act authorizes establishment of research institutes; also adds sec. 208(g) to PHS Act.).	Public Law 81-692, Aug. 15, 1950 (64 Stat. 443), S. 2591 (H.R. 3943) S. Rept. 1102, C. Rept. (H. Rept.) 2750.	To amend the PHS Act to support research and training in matters relating to arthritis and rheumatism, multiple sclerosis, cerebral palsy, epilepsy, poliomyelitis, blindness, leprosy, and other diseases.
7. Medical Facilities Survey and Construction Act of 1954.	Public Law 83-482, July 12, 1954 (68 Stat. 461), H.R. 8149, H. Rept. 1268, S. Rept. 1612.	To amend the hospital survey and construction provisions of the PHS Act to provide assistance to the States for surveying the need for diagnosis or treatment centers, for hospitals for the chronically ill and impaired, for rehabilitation facilities, and for nursing homes, and to provide assistance in the construction of such facilities through grants to public and nonprofit agencies, and for other purposes.
8. National Health Survey Act	Public Law 84-652, July 3, 1956 (70 Stat. 489), S. 3076, S. Rept. 1718, H. Rept. 2108.	To provide for a continuing survey and special studies of sickness and disability in the United States, and for periodic reports of the results thereof, and for other purposes.
9. Alaska Mental Health Enabling Act	Public Law 84-830, July 28, 1956 (70 Stat. 709), H.R. 6376, H. Rept. 1399, S. Rept. 2053, C. Rept. 2735.	To confer upon Alaska autonomy in the field of mental health, transfer from the Federal Government to the Territory the fiscal and functional responsibilities for the hospitalization of committed mental patients, and for other purposes. (Includes PHS grants to Alaska for mental health program.)
10. Health Research Facilities Act of 1956	Public Law 85-835, July 30, 1956 (70 Stat. 717), S. 849, S. Rept. 869, H. Rept. 2184, C. Rept. 2773.	To amend the PHS Act so as to provide for grants-in-aid to non-Federal public and nonprofit institutions for the constructing and equipping of facilities for research in the sciences related to health.
11. National Library of Medicine Act	Public Law 84-941, Aug. 3, 1956 (70 Stat. 960), S. 3430, S. Rept. 2071, H. Rept. 2826.	To amend title III of the PHS Act, and for other purposes. (Establishes in the PHS the National Library of Medicine.)
12. Health Amendments Act of 1956	Public Law 84-911, Aug. 2, 1956 (70 Stat. 923), S. 3958, S. Rept. 2070, H. Rept. 2569.	To improve the health of the people by assisting in increasing the number of adequately trained professional and practical nurses and professional public health personnel assisting in the development of improved methods of care and treatment in the field of mental health, and for other purposes.

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS
INCLUDED IN THE COMPILATION—Continued

Title	Public law	Purpose of the Act
13. Public Health Service Commissioned Corps Personnel Act of 1960.	Public Law 86-415, Apr. 8, 1960 (74 Stat. 32), S. 2220, S. Rept. 535, H. Rept. 1091.	To strengthen the Commissioned Corps of the Public Health Service through revision and extension of some of the provisions relating to retirement, appointment of personnel, and other related personnel matters, and for other purposes.
14. International Health Research Act of 1960 ..	Public Law 86-610, July 12, 1960 (74 Stat. 364), S.J. Res. 41 (H.J. Res. 649), S. Rept. 243.	* * * to provide for international cooperation in health research, research training, and research planning, and for other purposes. (Note: By error there was left in the purpose clause the phrase "to establish a National Institute for International Health and Medical Research" although as enacted, the law carried no such provision. We have used asterisks in lieu of that phrase to prevent confusion.)
15. Community Health Services and Facilities Act of 1961.	Public Law 87-395, Oct. 5, 1961 (75 Stat. 824), H.R. 4998, H. Rept. 599, S. Rept. 845, C. Rept. 1209.	To assist in expanding and improving community facilities and services for the health care of aged and other persons, and for other purposes.
16. (No authorized title—provides for PHS grants for family health clinics for migratory workers.)	Public Law 87-692, Sept. 25, 1962 (76 Stat. 592), S. 1130 (H.R. 12365), S. Rept. 699.	To amend title III of the PHS Act to authorize grants for family clinics for domestic agricultural migratory workers, and for other purposes.
17. (No authorized title—provides for establishment of an Institute of Child Health and Human Development and an Institute of General Medical Sciences; extends for 3 years research facilities construction program of title VII, PHS Act.)	Public Law 87-838, Oct. 17, 1962 (76 Stat. 1072), H.R. 11099, H. Rept. 1969, S. Rept. 2174.	To amend the PHS Act to provide for the establishment of an Institute of Child Health and Human Development, to extend for 3 additional years the authorization for grants for the construction of facilities for research in the sciences related to health, and for other purposes.
18. Vaccination Assistance Act of 1962	Public Law 87-868, Oct. 23, 1962 (76 Stat. 1155), H.R. 10541, H. Rept. 1835, S. Rept. 1907.	To assist States and communities to carry out intensive vaccination programs designed to protect their populations, particularly all preschool children, against poliomyelitis, diphtheria, whooping cough, and tetanus.
19. Health Professions Educational Assistance Act of 1963.	Public Law 88-129, Sept. 24, 1963 (77 Stat. 164), H.R. 12, H. Rept. 109, S. Rept. 485.	To increase the opportunities for training of physicians, dentists, and professional public health personnel, and for other purposes.
20. Sec. 101 of the Mental Retardation Facilities and Community Health Centers Construction Act of 1963.	Public Law 88-164, Oct. 31, 1963 (77 Stat. 282), S. 1576, S. Rept. 180, H. Rept. 694, C. Rept. 862.	To provide centers for research on mental retardation and related aspects of human development.
21. Hospital and Medical Facilities Amendments of 1964.	Public Law 88-443, Aug. 18, 1964 (78 Stat. 447), H.R. 10041, H. Rept. 1340, S. Rept. 1274.	To improve the public health through revising, consolidating, and improving the hospital and other medical facilities provisions of the Public Health Service Act.
22. Nurse Training Act of 1964	Public Law 88-581, Sept. 4, 1964 (78 Stat. 908), H.R. 11241, H. Rept. 1549, S. Rept. 1378.	To amend the Public Health Service Act to increase the opportunities for training professional nursing personnel, and for other purposes.
23. Community Health Services Extension Amendments of 1965.	Public Law 89-109, Aug. 5, 1965 (79 Stat. 435), S. 510 (H.R. 2986), S. Rept. 117, C. Rept. 676.	To extend and otherwise amend certain expiring provisions of the Public Health Service Act relating to community health services, and for other purposes.
24. Health Research Facilities Amendments of 1965.	Public Law 89-115, Aug. 9, 1965 (79 Stat. 448), H.R. 2984, H. Rept. 247, S. Rept. 367, C. Rept. 677.	To amend the Public Health Service Act provisions for construction of health research facilities by extending the expiration date thereof and providing increased support for the program, to authorize additional Assistant Secretaries in the Department of Health, Education, and Welfare, and for other purposes.
25. Heart Disease, Cancer, and Stroke Amendments of 1965.	Public Law 89-239, Oct. 6, 1965 (79 Stat. 926), S. 596 (H.R. 3140), S. Rept. 368.	To assist in combating heart disease, cancer, stroke, and related diseases.
26. Health Professions Educational Assistance Amendments of 1965.	Public Law 89-290, Oct. 22, 1965 (79 Stat. 1052), H.R. 3141, H. Rept. 781, S. Rept. 789.	To improve the educational quality of schools of medicine, dentistry, and osteopathy, to authorize grants under that Act to such schools for the awarding of scholarships to needy students and to extend expiring provisions of that Act for student loans and for aid in construction of teaching facilities for students in such schools and schools for other health professions, and for other purposes.
27. Medical Library Assistance Act of 1965.	Public Law 89-291, Oct. 22, 1965 (79 Stat. 1059), S. 597 (H.R. 3142), S. Rept. 756.	To provide for a program of grants to assist in meeting the need for adequate medical library services and facilities.

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS
INCLUDED IN THE COMPILATION—Continued

Title	Public law	Purpose of the Act
28. Comprehensive Health Planning and Public Health Services Amendments of 1966.	Public Law 89-749, Nov. 3, 1966, S. 3008 (H.R. 18231), S. Rept. 1665.	To amend the Public Health Service Act to promote and assist in the extension and improvement of comprehensive health planning and public health services, to provide for a more effective use of available Federal funds for such planning and services, and for other purposes.
29. Allied Health Professions Personnel Training Act of 1966.	Public Law 89-751, Nov. 3, 1966, H.R. 13196, H. Rept. 1628, S. Rept. 1722.	To amend the Public Health Service Act to increase the opportunities for training of medical technologists and personnel in other allied health professions, to improve the educational quality of the schools training such allied health professions personnel, and to strengthen and improve the existing student loan programs for medical, osteopathic, dental, podiatry, pharmacy, optometric, and nursing students, and for other purposes.
30. Partnership for Health Amendments of 1967	Public Law 90-174, Dec. 5, 1976, H.R. 6418, H. Rept. 538, S. Rept. 724, C. Rept. 974.	To amend the Public Health Service Act to extend and expand the authorizations for grants for comprehensive health planning and services, to broaden and improve the authorization for research and demonstrations relating to the delivery of health services, to improve the performance of clinical laboratories, and to authorize cooperative activities between the Public Health Service hospitals and community facilities, and for other purposes.
31. Health Manpower Act of 1968.	Public Law 90-490, August 16, 1968, S. 3095, S. Rept. 1307, H. Rept. 1634 (acc. H.R. 15757).	To amend the Public Health Service Act to extend and improve the programs relating to the training of nursing and other health professions and allied health professions personnel, the program relating to student aid for such personnel, and the program relating to health research facilities, and for other purposes.
32. Health Services Amendments of 1968.	Public Law 90-574, Oct. 15, 1968, H.R. 15758, H. Rept. 1536, S. Rept. 1454, C. Rept. 1924.	To amend the Public Health Service Act so as to extend and improve the provisions relating to regional medical programs, to extend the authorization of grants for health of migratory agricultural workers, to provide for specialized facilities for alcoholics and narcotic addicts, and for other purposes.
33. (No short title—extends authorizations for grants to schools of Public Health).	Public Law 91-208, Mar. 12, 1970, S. 2809 (H.R. 14790), S. Rept. 586, C. Rept. 855.	To amend the Public Health Service Act so as to extend for an additional period the authority to make formula grants to schools of public health, project grants for graduate training in public health and traineeships for professional public health personnel.
34. (No short title—extends the Migrant Health Act).	Public Law 91-209, Mar. 12, 1970, H.R. 14733, H. Rept. 711, S. Rept. 618, C. Rept. 853.	To amend the Public Health Service Act to extend the program of assistance for health services for domestic migrant agricultural workers, and for other purposes.
35. Community Mental Health Centers Amendments of 1970.	Public Law 91-211, Mar. 13, 1970, S. 2523, S. Rept. 583, H. Rept. 91-735 (acc. 14986), C. Rept. 856.	To amend the Community Mental Health Centers Act to extend and improve the program of assistance under that Act for community mental health centers and facilities for the treatment of alcoholics and narcotic addicts, to establish programs for mental health of children, and for other purposes.
36. Medical Library Assistance Extension Act of 1970.	Public Law 91-212, Mar. 13, 1970, H.R. 11702, H. Rept. 313, S. Rept. 480, C. Rept. 854.	To amend the Public Health Service Act to improve and extend the provisions relating to assistance to medical libraries and related instrumentalities, and for other purposes.
37. Medical Facilities Construction and Modernization Amendments of 1970.	Public Law 91-296, June 30, 1970, H.R. 11102, H. Rept. 262, S. Rept. 657, C. Rept. 1167.	To amend the Public Health Service Act to revise extend, and improve the program established by title VI of such Act, and for other purposes.
38. Communicable Disease Control Amendments of 1970.	Public Law 91-464, Oct. 16, 1970, S. 2264, S. Rept. 478, H. Rept. 1114 (acc. H.R. 11913), C. Rept. 1462.	To amend the Public Health Service Act to provide authorization for grants for communicable disease control and vaccination assistance.

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS
INCLUDED IN THE COMPILATION—Continued

Title	Public law	Purpose of the Act
39. Comprehensive Drug Abuse Prevention and Control Act of 1970.	Public Law 91-513, Oct. 27, 1970, H.R. 18583, H. Rept. 1444 (pts. 1 and 2) S. Rept. 613, C. Rept. 1603.	To amend the Public Health Service Act and other laws to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse.
40. (No short title—amends titles III and IX of the Public Health Service Act).	Public Law 91-515, Oct. 30, 1970, H.R. 17570, H. Rept. 1297, S. Rept. 1090, C. Rept. 1590.	To amend titles III and IX of the Public Health Service Act so as to revise, extend, and improve the programs of research, investigation, education, training, and demonstration authorized thereunder, and for other purposes.
41. Developmental Disabilities Services and Facilities Construction Amendments of 1970.	Public Law 91-517, Oct. 30, 1970, S. 2846, S. Rept. 757, H. Rept. 1277 (acc. H.R. 14237) C. Rept. 1589.	To amend the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1968 to assist the States in developing a plan for the provision of comprehensive services to persons affected by mental retardation and other development disabilities originating in childhood to assist the States in the provision of such services in accordance with such plan, to assist in the construction of facilities to provide the services needed to carry out such plan, and for other purposes.
42. Health Training Improvement Act of 1970 ...	Public Law 91-519, Nov. 2, 1970, S. 3586, S. Rept. 1002, H. Rept. 1266, C. Rept. 1588.	To amend title VII of the Public Health Service Act to establish eligibility of new schools of medicine, dentistry, osteopathy, pharmacy, optometry, veterinary medicine, and podiatry for institutional grants under section 771 thereof, to extend and improve the program relating to training of personnel in the allied health professions, and for other purposes.
43. Family Planning Services and Population Research Act of 1970.	Public Law 91-572, Dec. 24, 1970, S. 2108, S. Rept. 1004, H. Rept. 1472, C. Rept. 1667.	To promote public health and welfare by expanding, improving, and better coordinating the family planning services and population research activities of the Federal Government, and for other purposes. (adds Title X to the Public Health Service Act.)
44. Comprehensive Alcohol Abuse and Alcoholism Prevention Treatment and Rehabilitation Act of 1970.	Public Law 91-616, Dec. 31, 1970, S. 3835, S. Rept. 1069, H. Rept. 1663 (acc. H.R. 18874).	To provide a comprehensive Federal program for the prevention and treatment of alcohol abuse and alcoholism.
45. Emergency Health Personnel Act of 1970	Public Law 91-623, Dec. 31, 1970, S. 4106, S. Rept. 1194, H. Rept. 1662 (acc. H.R. 19860).	To amend the Public Health Service Act to authorize the assignment of commissioned officers of the Public Health Service to areas with critical medical manpower shortages, to encourage health personnel to practice in areas where shortages of such personnel exist, and for other purposes.
46. National Cancer Act of 1971	Public Law 92-218, Dec. 23, 1971, S. 1828, S. Rept. 247, H. Rept. 659 (acc. H.R. 11302), C. Repts. 722 (House), 565 (Senate).	To amend the PHS Act so as to strengthen the National Cancer Institute and the National Institutes of Health in order more effectively to carry out the national effort against cancer.
47. Communicable Disease Control Amendments Act of 1972.	Public Law 92-449, Sept. 30, 1972, S. 3442, S. Rept. 825, H. Rept. 1107 (acc. H.R. 14455), C. Repts. 1376 (House), 1087 (Senate).	To amend the PHS Act to extend and revise the program of assistance under that Act for the control and prevention of communicable diseases.
48. National Cooley's Anemia Control Act.	Public Law 92-414, Aug. 29, 1972, H.R. 15474, H. Rept. 437, S. Rept. 924.	To amend the PHS Act to provide assistance for programs for the diagnosis, prevention, and treatment of, and research in, Cooley's anemia.
49. Comprehensive Health Manpower Training Act of 1971.	Public Law 92-157, Nov. 18, 1971, H.R. 8629, H. Rept. 258, S. Rept. 251 (acc. S. 934), C. Repts. 578 (House), 398 (Senate).	To amend title VII of the PHS Act to provide increased manpower for the health professions, and for other purposes.
50. Emergency Health Personnel Act Amendments of 1972.	Public Law 92-585, Oct. 27, 1972, S. 3858, S. Rept. 1062, H. Rept. 1547 (acc. H.R. 16755).	To amend the PHS Act to improve the program of medical assistance to areas with health manpower shortages, and for other purposes.
51. National Heart, Blood Vessel, Lung, and Blood Act of 1972.	Public Law 92-423, Sept. 19, 1972, S. 3323, S. Rept. 733, H. Rept. 1108 (acc. H.R. 15081), C. Repts. 1349 (House), 1068 (Senate).	To amend the PHS Act to enlarge the authority of the National Heart and Lung Institute in order to advance the national attack against diseases of the heart and blood vessels, the lungs, and blood, and for other purposes.

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS
INCLUDED IN THE COMPILATION—Continued

Title	Public law	Purpose of the Act
52. (No short title)	Public Law 92-305, May 19, 1972, H.R. 13591, H. Rept. 940.	To amend the PHS Act to designate the National Institute of Arthritis and Metabolic Diseases as the National Institute of Arthritis, Metabolism, and for other purposes.
53. Nurse Training Act of 1971	Public Law 92-158, Nov. 18, 1971, H.R. 8630, H. Rept. 259, S. Rept. 252 (acc. S. 1747), C. Repts. 577 (House), 399 (Senate).	To amend title VIII of the PHS Act to provide for training increased numbers of nurses.
54. National Sickle Cell Anemia Control Act	Public Law 92-294, May 16, 1972, S. 2676, S. Rept. 557, H. Rept. 923.	To amend the PHS Act to provide for the control of sickle cell anemia.
55. (No short title—extends Solid Waste Disposal Act.)	Public Law 93-14, Apr. 9, 1973, H.R. 5446, H. Rept. 78.	To extend the Solid Waste Disposal Act, as amended, for 1 yr.
56. (No short title—extends Clean Air Act.)	Public Law 93-15, Apr. 9, 1973, H.R. 5445, H. Rept. 77.	To extend the Clean Air Act, as amended, for 1 yr.
57. Health Programs Extension Act of 1973	Public Law 93-45, June 18, 1973, S. 1136, S. Rept. 87, H. Rept. 227 (acc. H.R. 7806).	To extend through fiscal year 1974 certain expiring appropriations authorizations in the Public Health Service Act, the Community Mental Health Centers Act, and the Developmental Disabilities Services and Facilities Construction Act.
58. Emergency Medical Services System Act of 1973.	Public Law 93-154, Nov. 16, 1973, S. 2410, S. Rept. 397, H. Rept. 601 (acc. H.R. 10956).	To amend the Public Health Service Act to provide assistance and encouragement for the development of comprehensive area emergency medical services systems.
59. Health Maintenance Organization Act of 1973.	Public Law 93-222, Dec. 29, 1973, S. 14, S. Rept. 129, H. Rept. 451 (acc. H.R. 7974), C. Repts. 714 (House), 621 (Senate).	To amend the PHS Act to provide assistance and encouragement for the establishment and expansion of health maintenance organizations.
60. Sudden Infant Death Syndrome Act of 1974	Public Law 93-270, Apr. 22, 1974, S. 1745, S. Rept. 606, H. Rept. 758 (acc. H.R. 11386).	To provide financial assistance for research activities for the study of sudden death syndrome.
61. Narcotic Addict Treatment Act of 1974	Public Law 93-281, May 14, 1974, S. 1115, S. Rept. 192, H. Rept. 884 (acc. H.R. 12503).	To amend the Controlled Substances Act to provide for the registration of practitioners conducting narcotic treatment programs.
62. Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974.	Public Law 93-282, May 14, 1974, S. 1125, S. Rept. 208, H. Rept. 759 (acc. H.R. 11387).	To extend through fiscal year 1974 certain expiring appropriations authorizations in the Public Health Service Act, the Community Mental Centers Act, and the Developmental Disabilities Services and Facilities Construction Act.
63. Research on Aging Act of 1974	Public Law 93-296, May 31, 1974, S. 775, S. Rept. 299, H. Rept. 900 (acc. H.R. 6175).	To amend the PHS Act to provide for the establishment of a National Institute on Aging.
64. National Research Service Award Act of 1974.	Public Law 93-348, July 12, 1974, H.R. 7724, H. Rept. 224, S. Rept. 381, C. Rept. 1148 (House), 960 (Senate).	To amend the PHS Act to establish a program of National Research Service Awards to assure the continued excellence of biomedical and behavioral research and to provide for the protection of human subjects involved in biomedical and behavioral research.
65. National Cancer Amendments of 1974	Public Law 93-352, July 23, 1974, S. 2893, S. Rept. 736, H. Rept. 954 (acc. H.R. 13053), C. Rept. 1164 (House).	To amend the Public Health Service Act to improve the national cancer program and to authorize appropriations for such program for the next 3 fiscal years.
66. Health Services Research, Health Statistics, and Medical Libraries Act of 1974.	Public Law 93-353, July 23, 1974, H.R. 11385, S. Rept. 764, H. Rept. 757, C. Rept. 1170 (House).	To amend the PHS Act to revise the programs of health services research and to extend the program of assistance for medical libraries.
67. National Diabetes Mellitus Research and Education Act of 1974.	Public Law 93-354, July 23, 1974, S. 2830, S. Rept. 653, H. Rept. 894 (acc. H.R. 12417), C. Rept. 1147 (House).	To amend the PHS Act to provide for greater and more effective efforts in research and public education with regard to diabetes mellitus.
68. (No short title)	Public Law 93-385, Aug. 23, 1974, S. 3782, H. Rept. 1240 (acc. H.R. 16077).	To amend the Public Health Service Act to extend through fiscal year 1975 the scholarship program for the National Health Service Corps and the loan program for health professions students.
69. (No short title—extends the Controlled Substances Act.)	Public Law 93-481, Oct. 26, 1974, S. 3355, S. Rept. 925, H. Rept. 1248 (acc. H.R. 14215), C. Repts. 1442 (House), 1271 (Senate).	To amend the Controlled Substance Act to extend for 3 fiscal years the authorizations of appropriations for the administration and enforcement of that Act.
70. Safe Drinking Water Act	Public Law 93-523, Dec. 16, 1974, S. 433, S. Rept. 231, H. Rept. 1185 (acc. H.R. 13002).	To amend the Public Health Service Act to assure that the public is provided with safe drinking water.
71. (No short title—extends Solid Waste Disposal Act.)	Public Law 93-611, Jan 2, 1975, H.R. 16045, H. Rept. 1235, S. Rept. 1402.	To amend the Solid Waste Disposal Act to authorized appropriations for fiscal year 1975.

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS
INCLUDED IN THE COMPILATION—Continued

Title	Public law	Purpose of the Act
72. National Arthritis Act of 1974	Public Law 93-640, Jan. 4, 1975, S. 2854, S. Rept. 1251.	To amend the PHS Act to expand the authority of the National Institute of Arthritis, Metabolism, and Digestive Diseases in order to advance a national attack on arthritis.
73. National Health Planning and Resources Development Act of 1974.	Public Law 93-641, Jan. 4, 1975, S. 2994, S. Rept. 1285, H. Rept. 1382 (acc. H.R. 16204), C. Rept. 1640 (House).	To amend the PHS Act to assure the development of a national health policy and of effective State and area health planning and resources development programs.
74. (No short title—Health Services and Nurse Training Amendments.)	Public Law 94-63, July 29, 1975, S. 66, S. Rept. 94-29, H. Rept. 94-137 (acc. H.R. 4925), H. Rept. 94-143 (acc. H.R. 4115), H. Rept. 94-192 (acc. H.R. 4114), C. Rept. 94-348.	To amend the PHS Act and related laws to revise and extend the health revenue sharing program, the family planning program, the community mental health centers, the program for migrant health centers and community health centers, the National Health Service Corps program, and the programs for assistance for nurse training and for other purposes.
75. Developmentally Disabled Assistance and Bill of Rights Act.	Public Law 94-103, Oct. 4, 1975, H.R. 4005, H. Rept. 94-58, S. Rept. 94-160 (acc. S. 462), C. Rept. 94-473.	To amend the Developmental Disabilities Services and Facilities Construction Act to revise and extend the programs authorized by that Act.
76. Health Research and Health Services Amendments of 1976.	Public Law 94-278, Apr. 22, 1976, H.R. 7988, H. Rept. 94-498, S. Rept. 94-509 (acc. S. 988), C. Rept. 94-1005.	To amend the PHS Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study and report on the release of research information.
77. (No short title—National Health Information and Disease Prevention Act.)	Public Law 94-317, June 23, 1976, S. 1466, S. Rept. 94-330, H. Rept. 94-1007 (acc. H.R. 12678).	To amend the PHS Act to provide authority for health information and health promotion programs, to revise and extend authority for disease prevention and control programs, and to revise and extend authority for venereal disease programs, and to amend the Lead-Based Paint Poisoning Prevention Act to revise and extend that Act.
78. Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1976.	Public Law 94-371, July 26, 1976, S. 3184, S. Rept. 94-705 (parts 1 and 2), H. Rept. 94-1092 (acc. H.R. 12677), C. Rept. 94-1285.	To amend the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1976, and for other purposes.
79. National Swine Flu Immunization Program of 1976.	Public Law 94-380, Aug. 12, 1976, S. 3735, S. Rept. 94-1147 (see also remarks by Honorable Paul G. Rogers in Cong. Rec. for Aug. 26, 1976).	To amend the PHS Act to authorize the establishment and implementation of an emergency national swine flu immunization program and to provide an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine under such program.
80. Indian Health Care Improvement Act	Public Law 94-437, Sept. 30, 1976, S. 522, S. Rept. 94-133, H. Rept. 94-1026, parts I-IV (acc. H.R. 2525).	To implement the Federal responsibility for the care and education of the Indian people by improving the services and facilities of Federal Indian health programs and encouraging maximum participation of Indians in such programs, and for other purposes.
81. Health Maintenance Organization Amendments of 1976.	Public Law 94-460, Oct. 8, 1976, H.R. 9019, H. Rept. 94-518, S. Rept. 94-844 (acc. S. 1926), C. Rept. 94-1513.	To amend title XIII of the PHS Act to revise and extend the program for the establishment of HMO's.
82. Health Professions Educational Assistance Act of 1976.	Public Law 94-484, Oct. 12, 1976, H.R. 5546, H. Rept. 94-266, S. Rept. 94-886 and No. 94-887 (acc. S. 3239), C. Rept. 94-1612.	To amend the PHS Act to revise and extend the programs under title VII for training in the health and allied professions, to revise the National Health Service Corps program and the National Health Service Corps scholarship training program, and for other purposes.
83. Arthritis, Diabetes, and Digestive Diseases Amendments of 1976.	Public Law 94-562, Oct. 19, 1976, S. 2910	To amend the PHS Act to revise and extend provisions respecting arthritis and diabetes.
84. Emergency Medical Services Amendments of 1976.	Public Law 94-573, Oct. 21, 1976, S. 2548, S. Rept. 94-889, H. Rept. 94-1089 (acc. H.R. 12664).	To revise and extend the provisions of title XII of the PHS Act relating to emergency medical services systems; to establish programs relating to burn injuries, and for other purposes.
85. Health Planning and Health Services Research and Statistics Extension Act of 1977.	Public Law 95-83, Aug. 1, 1977, H.R. 4975, H. Repts. 95-117, 95-118, 95-500, S. Rept. 95-102.	To extend through fiscal year 1978 funding for health programs.

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS
INCLUDED IN THE COMPILATION—Continued

Title	Public law	Purpose of the Act
86. (No short title—revision of capitation grants.)	Public Law 95-215, Dec. 19, 1977, H.R. 9418, H. Repts. 95-707, 95-828, S. Rept. 95-545.	To revise the conditions under which schools may receive capitation grants under sec. 770 of the PHS Act.
87. Drug Abuse Prevention and Treatment Amendments of 1978.	Public Law 95-461, Oct. 14, 1978, S. 2916, S. Repts. 95-820, 95-151, H. Rept. 95-1187.	To amend the Drug Abuse Office and Treatment Act of 1972 to extend the programs of assistance under that Act.
88. Health Maintenance Organization Amendments of 1978.	Public Law 95-559, Nov. 1, 1978, S. 2534, S. Rept. 95-837, H. Repts. 95-1479, 95-1784.	To amend the PHS Act to revise and extend the program of assistance under title XIII for HMO's.
89. Title V of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978.	Public Law 95-602, Nov. 6, 1978, H.R. 12467, H. Rept. 95-1780.	To revise and extend the programs of assistance under the Developmental Disabilities Services and Facilities Construction Act.
90. (No short title—extension of title X and part B of title XI.)	Public Law 95-613, Nov. 8, 1978, S. 2522, S. Rept. 95-822, H. Rept. 95-1191.	To extend family planning assistance and sudden infant death assistance through fiscal year 1981.
91. Community Mental Health Center Extension Act of 1978 and Biomedical Research and Research Training Amendments of 1978.	Public Law 95-622, Nov. 9, 1978, S. 2450, S. Rept. 95-838, H. Repts. 95-1192, 95-1780.	To revise and extend the Community Mental Health Centers Act, to revise and extend the cancer and heart and lung programs, to revise and extend the National Research Services awards programs, and to establish the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.
92. Health Services Research, Health Statistics, and Health Care Technology Act of 1978.	Public Law 95-623, Nov. 9, 1978, S. 2466, S. Rept. 95-839, H. Repts. 95-1190, 95-1783.	To amend the PHS Act to revise and extend the authorities relating to health services research and health statistics and to establish a National Center for Health Care Technology.
93. Health Services and Centers Amendments of 1978.	Public Law 95-626, Nov. 10, 1978, S. 2474, S. Rept. 95-860, H. Repts. 95-1191, 95-1799.	To amend the PHS Act to revise and extend the programs for migrant and community health centers, to establish a program for primary health centers, to revise and extend secs. 314 and 317, to provide assistance to other preventive health service programs, to place home health services and lead-based paint programs in the PHS Act, and to establish an adolescent pregnancy program.
	Public Law 96-32, July 10, 1979, S.J. Res. 14, H. Rept. 96-187.	To amend the Public Health Service Act and related health laws to correct printing and other technical errors.
	Public Law 96-33, July 16, 1979, H.R. 4556	To amend section 1521 of the Public Health Service Act to authorize the Secretary of Health, Education, and Welfare to extend conditional designations of State health planning and development agencies.
	Public Law 96-63, Sept. 6, 1979, S. 1146, S. Rept. 96-161, H.R. 3509, H. Rept. 96-186.	To extend for 3 fiscal years the authorizations for appropriations under the Safe Drinking Water Act.
	Public Law 96-76, Sept. 29, 1979, S. 230, S. Rept. 96-101, H.R. 3633, H. Rept. 96-183.	To amend title VIII of the Public Health Service Act to extend through fiscal year 1980 the program of assistance for nurse training, and for other purposes.
94. Health Planning and Resources Development Amendments of 1979.	Public Law 96-79, Oct. 4, 1979, S. 544, S. Rept. 96-96, H.R. 3917, H. Rept. 96-190, S. Conf. Rept. 96-309.	To amend titles XV and XVI of the Public Health Service Act to revise and extend the authorities and requirements under those titles for health planning and health resources development, and for other purposes.
	Public Law 96-142, Dec. 12, 1979, S. 497, S. Rept. 96-102, H.R. 3642, H. Rept. 96-185.	To extend for 3 fiscal years the authorizations of appropriations under section 789 and title XII of the Public Health Service Act relating to emergency medical services, to revise and improve the authorities for assistance under such title XII, to increase the authorizations of appropriations and revise and improve the authorities for assistance under part B of title XI of such Act for sudden infant death syndrome counseling and information projects, and for other purposes.
95. Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1979.	Public Law 96-180, Jan. 2, 1980, S. 440, S. Rept. 96-103, H.R. 3916, H. Rept. 96-193.	To revise and extend the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970.
96. Mental Health Systems Act	Public Law 96-398, Oct. 7, 1980, S. 1177, S. Rept. 96-712, H.R. 7299, H. Rept. 96-977, H. Conf. Rept. 96-1367.	To improve the provision of mental health services and otherwise promote mental health throughout the United States, and for other purposes.

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS
INCLUDED IN THE COMPILATION—Continued

Title	Public law	Purpose of the Act
97. Health Programs Extension Act of 1980	Public Law 96-538, Dec. 17, 1980, S. 988, S. Rept. 96-714, H.R. 7036, H. Rept. 96-997, H. Conf. Rept. 96-1478.	To amend the Public Health Service Act to revise and extend the authorities under that Act relating to national research institutes, and for other purposes.
98. Omnibus Budget Reconciliation Act of 1981	Public Law 97-35, title IX, Aug. 13, 1981, H.R. 3982, S. 1377, S. Rept. 97-139, H. Rept. 97-158, H. Conf. Rept. 97-208..	To provide for reconciliation pursuant to section 301 of the first concurrent resolution on the budget for the fiscal year 1982.
99. Alcohol and Drug Abuse Amendments of 1983.	Public Law 98-24, Apr. 26, 1983, S. 126, S. Rept. 98-29. Public Law 98-49, July 13, 1983, H.R. 2713, H. Rept. 98-143.	To remedy alcohol and drug abuse. To amend the Public Health Service Act to authorize appropriations to be made available to the Secretary of Health and Human Services for research for the cause, treatment, and prevention of public health emergencies.
100. Rural Health Clinics Act of 1983	Public Law 98-194, Dec. 1, 1983, S. 2129	To provide revised reimbursement criteria for small rural health clinics utilizing National Health Service Corps personnel.
101. Alcohol and Drug Abuse Amendments of 1983.	Public Law 98-24, Apr. 26, 1983, S. 126, S. Rept. 98-29. Public Law 98-49, July 13, 1983, H.R. 2713, H. Rept. 98-143.	To remedy alcohol and drug abuse. To amend the Public Health Service Act to authorize appropriations to be made available to the Secretary of Health and Human Services for research for the cause, treatment, and prevention of public health emergencies.
102. Rural Health Clinics Act of 1983	Public Law 98-194, Dec. 1, 1983, S. 2129	To provide revised reimbursement criteria for small rural health clinics utilizing National Health Service Corps personnel.
103. National Organ Transplant Act	Public Law 98-507, Oct. 19, 1984, S. 2048, H.R. 4080, H. Rept. 98-575; H.R. 5580, H. Rept. 98-769; S. Rept. 98-382, H. Conf. Rept. 98-1127.	To provide for the establishment of the Task Force on Organ Transplantation and the Organ Procurement and Transplantation Network, to authorize financial assistance for organ procurement organizations, and for other purposes.
104. Alcohol Abuse, Drug Abuse, and Mental Health Amendments of 1984.	Public Law 98-509, Oct. 19, 1984, S. 2303, H. Conf. Rept. 98-1123, S. Rept. 98-381. Public Law 98-512, Oct. 19, 1984, S. 2616, H. Conf. Rept. 98-1154, S. Rept. 98-496.	To amend the Public Health Service Act to revise and extend the authorities of that Act for assistance for alcohol and drug abuse and mental health services. To revise and extend the programs of assistance under titles X and XX of the Public Health Service Act.
105. Developmental Disabilities Act of 1984	Public Law 98-527, Oct. 19, 1984, H.R. 5603, H. Rept. 98-826, H. Conf. Rept. 98-1074.	To revise and extend programs for persons with developmental disabilities.
106. Health Promotion and Disease Prevention Amendments of 1984.	Public Law 98-551, Oct. 30, 1984, S. 771, S. Rept. 98-158.	To revise and extend provisions of the Public Health Service Act relating to health promotion and disease prevention, to provide for the establishment of centers for research and demonstrations concerning health promotion and disease prevention, and for other purposes.
107. Preventive Health Amendments of 1984	Public Law 98-555, Oct. 30, 1984, S. 2301, H.R. 5538, H. Rept. 98-1063, S. Rept. 98-393.	To revise and extend programs for the provision of health services and preventive health services, and for other purposes.
108. Nurse Education Amendments of 1985	Public Law 99-92, Aug. 16, 1985, H.R. 2370, S. 1284, S. Rept. 99-106, H. Rept. 99-161.	To amend the Public Health Service Act to extend the programs of assistance for nurse education.
109. Health Services Amendments of 1985	Public Law 99-117, Oct. 7, 1985, S. 1689	To amend various provisions of the Public Health Service Act.
110. Health Professions Training Assistance Act of 1985.	Public Law 99-129, Oct. 22, 1985, H.R. 2410, S. 1283, S. Rept. 99-105, H. Rept. 99-145.	To amend the Public Health Service Act to revise and extend the programs under title VII of that Act.
111. Health Research Extension Act of 1985	Public Law 99-158, Nov. 20, 1985, H.R. 2409, S. 1309, S. Rept. 99-108, S. Conf. Rept. 99-157, H. Rept. 99-158, H. Conf. Rept. 99-309.	To amend the Public Health Service Act to revise and extend the authorities under that Act relating to the National Institutes of Health and National Research Institutes, and for other purposes.
112. Injury Prevention Act of 1986	Public Law 99-649, Nov. 10, 1986, S. 2648, S. Rept. 99-434.	To improve the public health through the prevention of injuries.
113. Stewart B. McKinney Homeless Assistance Act.	Public Law 100-77, Sec. 601-602 & 611-613, July 22, 1987, H.R. 558, H.R. 177, H. Rept. 100-10, H. Rept. 100-8, H. Conf. Rept. 100-174.	To provide urgently needed assistance to protect and improve the lives and safety of the homeless, with special emphasis on elderly persons, handicapped persons, and families with children.
114. Excellence in Minority Health Education and Care Act.	Public Law 100-97, Aug. 18, 1987, S. 769, S. Rept. 100-110.	To provide grants to support excellence in minority health professions education.
115. Developmental Disabilities Assistance and Bill of Rights Act Amendments of 1987.	Public Law 100-146, Oct. 29, 1987, S. 1417, H. Rept. 100-265, S. Rept. 100-113.	To amend the Developmental Disabilities Assistance and Bill of Rights Act to extend the programs established in such Act, and for other purposes.

**MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS
INCLUDED IN THE COMPILATION—Continued**

Title	Public law	Purpose of the Act
116. Health Care Services in the Home Act of 1987.	Public Law 100-175, Sec. 602, Nov. 29, 1987, H.R. 1451, H. Rept. 100-97, H. Conf. Rept. 100-427.	To amend the Older Americans Act of 1965 to authorize appropriations for the fiscal years 1988, 1990, and 1991; to amend the Native Americans Programs Act of 1974 to authorize appropriations for such fiscal year, and for other purposes.
117. Public Health Service Amendments of 1987	Public Law 100-177, December 1, 1987, S. 1158, S. Rept. 100-108.	To amend the Public Health Service Act to establish a National Health Service Corps Loan Repayment Program and to otherwise revise and extend the program for the National Health Service Corps.
118. Omnibus Budget Reconciliation Act of 1987	Public Law 100-203, Sec. 4052 & 4301-4307, December 22, 1987, H.R. 3545, H. Rept. 100-391, H. Conf. Rept. 100-495.	To provide for reconciliation pursuant to section 4 of the concurrent resolution on the budget for the fiscal year 1988.
119. Community and Migrant Health Centers Amendments of 1988.	Public Law 100-386, August 10, 1988, S. 2385, S. Rept. 100-343.	To amend the Public Health Service Act to revise and extend the programs establishing migrant health centers and community health centers. Public Law 100-509.
120. Protection and Advocacy for Mentally Ill Individuals Amendments Act of 1988.	Public Law 100-509, October 20, 1988, S.2393, H. Rept. 100-903, S. Rept. 100-454.	To amend the Protection and Advocacy for Mentally Ill Individuals Act of 1986 to reauthorize such Act, and for other purposes.
121. Health Maintenance Organization Amendments of 1988.	Public Law 100-517, October 24, 1988, H.R. 3235, H. Rept. 100-417, S. Rept. 100-304, H. Conf. Rept. 100-1056.	To amend the Public Health Service Act to revise the program of assistance for health maintenance organizations.
122. National Deafness and Other Communication Disorders Act of 1988.	Public Law 100-553, Sec. 2, October 28, 1988, S. 1727.	To amend the Public Health Service Act to establish within the National Institutes of Health a National Institute on Deafness and Other Communication Disorders.
123. Lead Contamination Control Act of 1988	Public Law 100-572, Sec. 3, October 31, 1988, H.R. 4939, H. Rept. 100-1041.	To amend the Safe Drinking Water Act to control lead in drinking water.
124. Clinical Laboratory Improvement Amendments of 1988.	Public Law 100-578, October 31, 1988, H.R. 5471.	To amend the Public Health Service Act to revise the authority for the regulation of clinical laboratories.
125. Health Omnibus Programs Extension of 1988.	Public Law 100-607, November 4, 1988, S. 2889.	To amend the Public Health Service Act to establish certain health programs, to revise and extend certain health programs, and for other purposes.
126. Stewart B. McKinney Homeless Assistance Amendments Act of 1988.	Public Law 100-628, Title VI, November 7, 1988, H.R. 4352, H. Rept. 100-718, S. Rept. 100-343, H. Conf. Rept. 100-1089.	To amend the Stewart B. McKinney Homeless Assistance Act to extend programs providing urgently needed assistance for the homeless, and for other purposes.
127. Technical and Miscellaneous Revenue Act of 1988.	Public Law 100-647, Sec. 3011(b)(7), November 10, 1988, H.R. 4333, H. Rept. 100-795, S. Rept. 100-445, H. Conf. Rept. 100-1104.	To make technical corrections relating to the Tax Reform Act of 1986, and for other purposes.
128. Anti-Drug Abuse Act of 1988	Public Law 100-690, Sec. 1007(c) & Title II, November 18, 1988, H.R. 5210.	To prevent the manufacturing, distribution, and use of illegal drugs, and for other purposes.
129. Indian Health Care Amendments of 1988	Public Law 100-713, Sec. 104(b), 106, & 714, November 23, 1988, H.R. 5261, S. Rept. 100-508, H. Conf. Rept. 100-1075.	To reauthorize and amend the Indian Health Care Improvement Act, and for other purposes.
130. Drug Abuse Treatment Technical Corrections Act of 1989.	Public Law 101-93, August 16, 1989, H.R. 1426.	To amend the Public Health Service Act to make technical corrections relating to subtitles A and G of title II of the Anti-Drug Abuse Act of 1988, and for other purposes.
131. (No short title—construction of biomedical facilities).	Public Law 101-190, November 29, 1989, S. 1390, S. Rept. 101-101.	To provide for the construction of biomedical facilities in order to ensure a continued supply of specialized strains of mice essential to biomedical research in the United States, and for other purposes.
132. Omnibus Budget Reconciliation Act of 1989	Public Law 101-239, December 19, 1989, H.R. 3299.	To provide for reconciliation pursuant to section 5 of the concurrent resolution on the budget for the fiscal year 1990.
133. Breast and Cervical Cancer Mortality Prevention Act of 1990.	Public Law 101-354, August 10, 1990, H.R. 4790.	To amend the Public Health Service Act to establish a program of grants for the detection and control of breast and cervical cancer.
134. Tuberculosis Prevention Amendments of 1990.	Public Law 101-368, August 15, 1990, H.R. 4273.	To amend the Public Health Service Act to extend the program of grants for preventive health services with respect to tuberculosis, and for other purposes.
135. Drug Abuse Treatment Waiting Period Reduction Amendments of 1990.	Public Law 101-374, August 15, 1990, S. 2461.	To amend the Public Health Service Act to revise and extend the program of grants for reducing the waiting period for receiving treatment services for drug abuse, and for other purposes.

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS
INCLUDED IN THE COMPILATION—Continued

Title	Public law	Purpose of the Act
136. Ryan White Comprehensive Aids Resources Emergency Act of 1990.	Public Law 101-381, August 18, 1990, S. 2240.	To amend the Public Health Service Act to provide grants to improve the quality and availability of care for individuals and families with HIV disease, and for other purposes.
137. Vaccine and Immunization Amendments of 1990.	Public Law 101-502, November 3, 1990, H.R. 4238.	To amend the Public Health Service Act to extend various programs with respect to vaccine-prevention diseases.
138. Treasury, Postal Service and General Government Appropriations Act, 1991.	Public Law 101-509, November 5, 1990, H.R. 5241.	Making appropriations for the Treasury Department, the United States Postal Service, the Executive Office of the President, and certain independent Agencies, for the fiscal year ending September 30, 1991.
139. Disadvantaged Minority Health Improvement Act of 1990.	Public Law 101-527, November 6, 1990, H.R. 5702.	To amend the Public Health Service Act to improve the health of individuals who are members of minority groups and who are from disadvantaged backgrounds, and for other purposes.
140. Home Health Care and Alzheimer's Disease Amendments of 1990.	Public Law 101-557, November 15, 1990, H.R. 5112.	To amend the Public Health Service Act regarding certain programs for health care services in the home and certain programs relating to Alzheimer's disease, and for other purposes.
141. Injury Control Act of 1990	Public Law 101-558, November 15, 1990, H.R. 5113.	To amend the Public Health Service Act to revise and extend the program for the prevention and control of injuries.
142. Trauma Care Systems Planning and Development Act of 1990.	Public Law 101-590, November 16, 1990, H.R. 1602.	To amend the Public Health Service Act to improve emergency medical services and trauma care, and for other purposes.
143. National Health Service Corps Revitalization Amendments of 1990.	Public Law 101-597, November 16, 1990, H.R. 4487.	To amend the Public Health Service Act to revise and extend the program for the National Service Corps, and to establish certain programs of grants to the States for improving health services in the States.
144. National Institutes of Health Amendments of 1990.	Public Law 101-613, November 16, 1990, S. 2857, (H.R. 5661).	To amend the Public Health Service Act with respect to certain programs for the National Institutes of Health.
145. Transplant Amendments Act of 1990	Public Law 101-616, November 16, 1990, S. 2946.	To amend the Public Health Service Act to revise and extend the program establishing the National Bone Marrow Donor Registry, and for other purposes.
146. Safe Medical Devices Act of 1990	Public Law 101-629, November 28, 1990, H.R. 3095.	To amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.
147. Mental Health Amendments of 1990	Public Law 101-639, November 28, 1990, S. 2628.	To amend the Public Health Service Act to reauthorize certain National Institute of Mental Health grants and to improve provisions concerning the State comprehensive mental health services plan, and for other purposes.
148. Indian Arts and Crafts Act of 1990	Public Law 101-644, November 29, 1990, H.R. 2006.	To expand the powers of the Indian Arts and Crafts Board, and for other purposes.
149. Stewart B. McKinney Homeless Assistance Amendments Act of 1990.	Public Law 101-645, November 29, 1990, H.R. 3789.	To amend the Stewart B. McKinney Homeless Assistance Act to extend programs providing urgently needed assistance for the homeless, and for other purposes.
150. Crime Control Act of 1990	Public Law 101-647, November 29, 1990, S. 3266, (H.R. 5269).	To control crime,
151. Persian Gulf Conflict Supplemental Authorization and Personnel Benefits Act of 1991.	Public Law 102-25, April 6, 1991, S. 724 ..	Persian Gulf Conflict Supplemental Authorization and Personnel Benefits Act of 1991.
152. Terry Beinr Community Based AIDS Research Initiative Act of 1991.	Public Law 102-96, August 14, 1991, S. 1594.	To honor and commend the efforts of Terry Beinr, to amend the Public Health Service Act to rename and make technical amendments to the community-based AIDS research initiative, and for other purposes.
153. Health Information, Health Promotion, and Vaccine Injury Compensation Amendments of 1991.	Public Law 102-168, November 26, 1991, H.R. 3402.	To amend the Public Health Service Act to revise and extend certain programs regarding health information, health promotion, and vaccine injury compensation.
154. (No short title)	Public Law 102-54, June 13, 1991, H.R. 232.	To amend title 38, United States Code, with respect to veterans programs for housing and memorial affairs.

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS
INCLUDED IN THE COMPILATION—Continued

Title	Public law	Purpose of the Act
155. ADAMHA Reorganization Act	Public Law 102-321, July 10, 1992, S. 1306.	To amend the Public Health Service Act to restructure the Alcohol, Drug Abuse, and Mental Health Administration and the authorities of such Administration, including establishing separate block grants to enhance the delivery of services regarding drug abuse and mental health, and for other purposes.
156. Public Health Service Act Technical Amendments Act.	Public Law 102-352, August 26, 1992, S. 3112.	To amend the Public Health Service Act to make certain technical corrections, and for other purposes.
157. Health Professions Education Extension Amendments of 1992.	Public Law 102-408, October 13, 1992, H.R. 3508.	To amend the Public Health Service Act to revise and extend certain programs relating to the education of individuals as health professionals, and for other purposes.
158. DES Education and Research Amendments of 1992.	Public Law 102-409, October 13, 1992, H.R. 4178.	To amend the Public Health Service Act to provide for a program to carry out research on the drug known as diethylstilbestrol, to educate health professionals and the public on the drug, and to provide for certain longitudinal studies regarding individuals who have been exposed to the drug.
159. Agency for Health Care Policy and Research Reauthorization Act of 1992.	Public Law 102-410, October 13, 1992, H.R. 5673.	To amend the Public Health Service Act to revise and extend the programs of the Agency for Health Care Policy and Research.
160. Federally Supported Health Centers Assistance Act of 1992.	Public Law 102-501, October 24, 1992, H.R. 6183.	To amend the Public Health Service Act to provide protections from legal liability for certain health care professionals providing services pursuant to such Act.
161. Alzheimer's Disease Research, Training, and Education Amendments of 1992.	Public Law 102-507, October 24, 1992, S. 1577.	To amend the Alzheimer's Disease and Related Dementias Services Research Act of 1986 to reauthorize the Act, and for other purposes.
162. Cancer Registries Amendment Act	Public Law 102-515, October 24, 1992, S. 3312.	Entitled the "Cancer Registries Amendment Act".
163. Preventive Health Amendments of 1992	Public Law 102-531, October 27, 1992, H.R. 3635.	To amend the Public Health Service Act to revise and extend the program of block grants for preventive health services, and for other purposes.
164. Mammography Quality Standards Act of 1992.	Public Law 102-539, October 27, 1992, H.R. 6182.	To amend the Public Health Service Act to establish the authority for the regulation of mammography services and radiological equipment, and for other purposes.
165. Veterans Health Care Act of 1992	Public Law 102-585, November 4, 1992, H.R. 5193.	To amend title 38, United States Code, to improve health care services for women veterans, to expand authority for health care sharing agreements between the Department of Veterans Affairs and the Department of Defense to revise certain pay authorities that apply to Department of Veterans Affairs nurses, to improve preventive health services for veterans, to establish discounts on pharmaceuticals purchased by the Department of Veterans Affairs, to provide for a Persian Gulf War Veterans Health Registry, and to make other improvements in the delivery and administration of health care by the Department of Veterans Affairs.
166. National Institutes of Health Revitalization Act of 1993.	Public Law 103-43, June 10, 1993, S. 1	To amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes.
167. Omnibus Budget Reconciliation Act of 1993	Public Law 103-66, August 10, 1993, H.R. 2264.	To provide for reconciliation pursuant to section 7 of the concurrent resolution on the budget for fiscal year 1994.
168. Preventive Health Amendments of 1993	Public Law 103-183, December 14, 1983, H.R. 2202.	To amend the Public Health Service Act to revise and extend the program of grants relating to preventive health measures with respect to breast and cervical cancer.

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS
INCLUDED IN THE COMPILATION—Continued

Title	Public law	Purpose of the Act
169. Developmental Disabilities Assistance and Bill of Rights Act Amendments of 1994.	Public Law 103-230, April 6, 1994, S. 1284	To amend the Developmental Disabilities Assistance and Bill of Rights Act to modify certain provisions relating to programs for individuals with developmental disabilities, Federal assistance for priority area activities for individuals with developmental disabilities, protection and advocacy of individual rights, university affiliated programs, and projects of national significance, and for other purposes.







ISBN 0-16-047403-5





Public Health Service Act

Developmental Disabilities Assistance and Bill of Rights Act

Mental Health Systems Act

Consumer-Patient Radiation Health and Safety Act of 1981

Drug Abuse Prevention, Treatment, and Rehabilitation Act

Protection and Advocacy for Mentally Ill Individuals Act of 1986

Health Care Quality Improvement Act of 1986

Alzheimer's Disease and Related Dementias Services Research Act of 1986

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